IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
WESTERN DIVISION

GEORGE LEUS **715 Volker** **Apt. No. 18** **Fairfax, Missouri 64446,** **Plaintiff,**	)	
vs.	)	**Case No.:**
C.R. BARD, INC. **730 Central Avenue** **Murray Hill, New Jersey 07974,** **Serve: Registered Agent** **Jean F. Holloway** **730 Central Avenue** **Murray Hill, NJ 07974**	)	**DEMAND FOR TRIAL BY JURY**
and	)	
BARD PERIPHERAL VASCULAR, INC. **1415 West Third Street** **Suite 109** **Tempe, Arizona 85281** **Serve: Registered Agent** **CT Corporation System** **2390 E. Camelback Road** **Phoenix, Arizona 85016,**	)	
and	)	
DOE DEFENDANTS **1 Thru 20, Inclusive,** **Defendants.**	)	

COMPLAINT

COMES NOW Plaintiff George Leus and for his cause of action against Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. states and alleges as follows:

JURISDICTION AND VENUE

1. Plaintiff George Leus is a resident of the State of Missouri.
2. Defendant C.R. Bard, Inc., is, and was at all times relevant hereto, a domestic for-profit corporation in good standing, organized under the laws of the state of New Jersey ("C.R. Bard"). Defendant C.R. Bard, Inc., is, and was at all times relevant hereto, in the business of manufacturing, designing, assembling, distributing, marketing, advertising, transporting and selling "inferior vena cava filters" (hereinafter known as "IVC filters").
3. Defendant C.R. Bard, Inc., is, and was at all times relevant hereto, transacting, operating and conducting business within the State of Missouri where it advertised, sold and distributed the subject IVC filters including, but not limited to the Recovery Filter System, G2 Express and the G2 Vena Cava Filter which is the subject matter of this litigation. Defendant C.R. Bard, Inc., had at all times relevant hereto, substantial, systematic and continuous contact with the State of Missouri such that the exercise of personal jurisdiction over Defendant C.R. Bard is fair, just and appropriate.
4. Defendant Bard Peripheral Vascular, Inc. ("Bard Peripheral"), is, and was at all times relevant hereto, a domestic for-profit corporation in good standing, organized under the laws of the State of Arizona. Defendant Bard Peripheral Vascular Inc., is, and was at all times relevant hereto, in the business of manufacturing, designing, marketing, advertising, assembling, distributing, transporting and selling IVC filters.
5. Defendant Bard Peripheral Vascular, Inc., is, and was at all times relevant hereto,

transacting, operating and conducting business within the State of Missouri where it advertised, sold and distributed IVC filers, including, but not limited to the Recovery Filter System, G2 Express and the G2 Vena Cava Filter which is the subject matter of this litigation. Defendant Bard Peripheral Vascular, Inc., had at all times relevant hereto, substantial, systematic and continuous contract within the state of Missouri such that the exercise of personal jurisdiction over Bard Peripheral is fair, just and appropriate.

6. Plaintiff does not currently know the indentity of Does 1-20 inclusive. Plaintiff alleges that each Doe Defendant is legally responsible in some manner for damages sought herein.

7. Each Defendant has been the parent-subsidiary, alter-ego, agent, apparent agent, joint venturer, representative, or employee of each of the remaining defendants, and in the conduct alleged herein, each has been acting within the course and scope of said parent-subsidiary relationship, employment, or joint venture with the advanced knowledge, acquiescence, or subsequent ratification of each and every remaining Defendant.

8. The Court has diversity jurisdiction under 28 U.S.C. 1332 and the finder of fact could reasonably conclude the damages suffered by Plaintiff exceed $75,000.00.

9. Venue is proper under 28 U.S.C. 1391 (c).

10. Plaintiff has a cause of action pursuant to R.S. MO 537.00 et seq. in that Defendants are corporations which have sufficient minimum contacts with the State of Missouri to establish personal jurisdiction.

ALLEGATIONS COMMON TO ALL COUNTS

11. Defendant's C.R. Bard and Bard Peripheral designed, manufactured, assembled, tested, inspected, installed, advertised, marketed, distributed and sold an IVC Filter whose trade

name was a “G2 Vena Cava Filter” and/or G2 Filter System Femoral (Hereinafter known as the “G2 Filter”)

12. An IVC Filter is a device that is designed to filter or “catch” blood clots (called “thrombi”) that travel from the lower portions of the body to the heart and lungs. IVC filters may be designed to be implanted, either permanently or temporarily, in the human body, commonly, within the inferior vena cava. The inferior vena cava is a vein that returns the blood to the heart from the lower portions of the body. For various reasons, thrombi travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. These thrombi are called “deep vein thrombosis’” or “DVT”. DVT presents grave risks to human health.

13. Certain people are at risk for the development of DVT when undergoing certain surgical procedures such as gastric by-pass surgery. A physician may recommend surgically implanting an IVC filter to prevent thromboembolitic events.

14. Defendants designed, manufactured, marketed and sold IVC, filters from 2002 until the present.

15. Defendants initially designed, manufactured and sold an IVC Filter called the Recovery Filter System starting in 2002. The Recovery Filter system was constructed of nickel-titanium alloy (also called “Nitinol”). This composite material is unique as it possesses “shape memory”. That is, Nitinol will change shape according to change in temperature, and then, retake its prior shape after returning to its initial temperature. This quality makes Nitinol appealing for use in certain medical devices, including IVC filters.

16. In 2005, Defendants pulled the Recovery Filter System from the market only two (2) years after its introduction to the market.

17. The Recovery Filter System resembles an “upside down umbrella” with the fabric removed. It consists of twelve “struts” or legs. There are six (6) long struts and six shorter struts. The shorter struts are positioned above the longer struts. All of the struts are held together by a Nitinol “cap” located at the top of the device. The shorter struts were designed to be “centering” or “positioning” struts to assist in the proper centering of the filter when placed within the vena cava. The Recovery Filter System is inserted into the human body in endovascular fashion, typically by an interventional radiologist. It is inserted via catheter that is guided by a physician through a blood vessel into the inferior vena cava.

18. The Recovery Filter System was pulled from the market by Defendants because it was prone to failure following placement within the human body. The Recovery Filter System was prone to failure because the “struts” were likely to fracture and then, migrate to locations within the human body, it was predisposed to a high incidence of penetration and perforation of the walls of the vena cava, likely to “tilt” following placement and prone to bending and metal fatigue.

19. In the event of the penetration and/or perforation of the vena cava, the perforating strut becomes fixed in its position and resists flexion or movement. The fixed struts then become subjected to a high frequency of bending stress due to the vena cava wall’s movement during normal respiration and cardiac cycles. This leads to metal fatigue in the strut, at a point just below the cap.

20. On or about late 2004, Defendants made a decision to introduce a substitute vena cava filter for the Recovery Filter System.This substitute was the G2 Filter (“G2” stands for second generation of the Recovery Filter”).

21. The G2 Filter is the successor device to the Recovery Filter System and is constructed of Nitinol and designed to filter blood clots (thrombi) from the human circulatory system.

22. The design of the G2 Filter is similar to that of the Recovery Filter System. The only difference in design of the G2 Filter, as compared to the Recovery Filter System is dimensional and angular. For all other purposes, the G2 Filter is similar to its predecessor the Recovery Filer System. The G2 Filter has six (6) upper struts used for device positioning and filtering and, six (6) lower struts used for anchoring and filtering.

23. The Recovery Filter System and G2 Filter are made of the same alloy material and both manufactured of Nitinol alloy.

24. The G2 Filter is also inserted via catheter that is guided by a Physician (typically an interventional radiologist) through a blood vessel into the inferior vena cava.

25. The G2 Filter was advertised by Defendants to have “enhanced fracture resistance”, “improved centering” and “increased migration resistance.”

26. The G2 Filter was designed, manufactured, advertised and sold as a permanent placement vena cava filter to be permanently implanted in the human body.

27. The G2 Filter was designed so as to be unable to withstand the normal anatomical and physiological loading cycles exerted in vivo. It is of insufficient integrity and strength to withstand normal placement within the human body.

28. The G2 Filter was plagued with manufacturing defects, namely lack of preparation of the exterior surface of the device so as to eliminate “drawing marks.”

29. The global stressors of the respiratory and cardiac cycles of the human body cause the G2 Filter to develop stress or “fatigue” fractures of the Nitinol surface of the device. This results in fracture of one or more of the struts of the device. The struts will then become

imbedded in the anatomy, piercing tissue and organs.

30. The manufacturing defect of the G2 Filter includes, but is not limited to, the existence of "draw markings" and circumferential grinding markings on the Nitinol exterior of the surface of the device. The presence of these draw markings and/or circumferential grinding markings compromise the structural integrity of the G2 Filter while in vivo. The G2 Filter is prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the device. The G2 Filter is not of sufficient strength to withstand normal placement within the human body because of cracks, flaws and gouges in the alloy which makes up the device. The presence of the aforementioned exterior defects make the device more significantly susceptible to fatigue, failure and fracture.
31. The failure (fracture, perforation and/or migration) of these devices leads to a number of different complications, including, but not limited to perforation of tissue, vessels and/or organs.
32. Nitinol alloy is used in a number of different medical device applications. It is beneficial for these applications and is employed as material in stents and other medical device applications. It is also used in the manufacture of the G2 Filter, and other brands of IVC filters.
33. Specific manufacturing processes need to be utilized when using Nitinol as a component for medical devices, including IVC filters. Primarily, the Nitinol material should be electro-polished prior to assembly of the finished medical device.
34. Electro-polishing is a manner of removing surface blemishes, "draw marking" and circumferential grinding markings on the exterior of the surface of the Nitinol material. As mentioned supra, the existence of these surface blemishes, "draw markings" and

"circumferential grind-markings" causes/results in the weakening of the structural integrity of the end product, whether it is an IVC filter or other medical device.

35. For years, it has been known by manufacturers of the Nitinol medical devices and the medical device industry that electro-polishing Nitinol results in increased structural integrity of the device and resistance to fatigue and fatigue failures.

36. The exterior surfaces of the G2 Filters were not electro-polished prior to completion of the manufacturing process. This is a manufacturing defect that exists in the Recovery Filter System and G2 Filters which causes these filters to be structurally weak and susceptible to a significant risk of failure/fracture.

37. In 2008, Defendants introduced another version of the G2 Filter called the "G2 Express". The sole difference between the G2 Filter and the G2 Express is that the G2 Express has a "snare" or "hook" at the top of the filter to allow an explanting Physician an optional way to attempt to snare or hook the top of the device to retrieve the filter if possible and/or required.

38. In 2010, Defendants began marketing a "new" vena cava filter called the "Eclipse" vena cava filter. The Eclipse filter is identical to the G2 Express except for one important difference; the surface of the Eclipse filter is electro-polished. Defendants have represented that the Eclipse filter is substantially similar to the predicate device-the G2 Filter.

39. Defendants introduced the Eclipse filter because:

    a. the Recovery Filter System, G2 Filter and G2 Express filters were not electro-polished;

    b. it is standard in the industry, and has been for years, to electro-polish Nitinol

medical devices including vena cava filters;

c. the Recovery Filter System, G2 Filter and G2 Express filters were experiencing significantly increased rates of failure/fracture due to the fact that they were not electro-polished

40. Defendants were aware and had knowledge of the fact that the G2 Filter was defective and unreasonably dangerous as a result of the manufacturing process and due to filter failure and were causing injury and death to patients who had received the G2 Filter.

41. Defendants knew that the G2 Filer was at a high risk of filter failure due to lack of electro-polishing of the devices.

42. Defendants acted with a complete indifference to or conscious disregard for the safety of others, including Plaintiff, when it had actual knowledge of the defective and dangerous condition of the G2 Filter, yet continued to place said product in the stream of commerce and consciously took no steps to (1) inform or warn Plaintiff, his physicians, or the public at large of said dangers and (2) recall the G2 Filters from the market in a timely and safe fashion. Defendants acted in a willful, wanton and malicious manner and in total disregard for the health and safety of the users of the G2 Filter, including Plaintiff, to serve their own interests and having reason to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to Plaintiff and to other persons. Defendants acted in a willful, wanton and malicious manner and with a complete indifference to or conscious disregard for the safety of others, including Plaintiff when it fraudulently concealed from Plaintiff, the public at large and/or the medical community facts concerning the hazards associated

with the G2 Filter.

43. Defendants acted to serve their own interests and having reason to know and consciously disregarding the substantial risk that their product might kill or substantially harm patients, consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

44. On or about June 17, 2008 a G2 Filter (REF-310-LOT GFRA0592) manufactured, designed, assembled, distributed, marketed and sold by Defendants was surgically placed in Plaintiff's inferior vena cava.

45. On or about July 18, 2012 Plaintiff suffered an acute onset of bilateral lower extremity pain and swelling. He presented to the emergency room and was admitted to the ICU where he complained of the inability to move or feel his legs. A lower extremity ultrasound was performed which showed Plaintiff had an extensive bilateral lower extremity DVT (deep vein thrombosis) involving the entirety of both lower extremities, extending into the illiac arteries. A CT Scan of the abdomen and pelvis showed the IVC filter had several prongs extending outside of the vascular lumen of the inferior vena cava. As a direct and proximate result of said damage and perforation of the inferior vena cava caused by the IVC filter, Plaintiff suffered DVT and a complete thrombosis and occlusion of the inferior vena cava, pelvic veins and lower extremity bilaterally resulting in phlegmasia and lower extremity ischmeia requiring bilateral above-knee amputations. In addition, Plaintiff's hospital course was complicated by scrotal swelling. He underwent a partial scrotalectomy secondary to scrotal infarcts due to blood clots. Plaintiff was transferred to a nursing home upon discharge from the hospital for rehabilitation but re-admitted to the hospital as a result of an infection to his left above-

knee amputation stump and his treatment included debridement surgery and I.V. antibiotic therapy.

46. At all times relevant hereto, Defendants were responsible for inspecting the G2 Filter to insure that it was in proper working condition.

47. At all times relevant hereto, the G2 Filter was defective and unreasonably dangerous when placed into the stream of commerce by Defendants. Defendants, as manufacturers of medical devices to be used by the general public, owed a duty to Plaintiff and users of their IVC filters, including but not limited to the G2 Filter, to provide them with a safe product, free from any defect(s) that make said product defective and/or dangerous.

48. Defendants knew prior to manufacturing the G2 Filters and placing them into the stream of commerce that they were defective and unreasonably dangerous due to filter failure, including, but not limited to piercing/perforation of tissue, fracture and/or migration.

49. Section 15 (b) of the Consumer Product Safety Act, as amended (CPSA) 15 U.S.C 2064 (b)) requires every manufacturer, distributer, and retailer of a consumer product distributed in commerce who obtains information which reasonably supports the conclusion that the product contains a defect which "could" create a substantial product hazard [or] creates an unreasonable risk of serious injury or death to immediately inform the Consumer Product Safety Commission.

50. Defendants obtained information prior to manufacturing and selling the G2 Filters which reasonably supported the conclusion that the G2 Filters contained defects in the form of filter failure which could create a substantial product hazard [or] created an unreasonable risk of serious injury or death.

51. Defendants had a duty to inform the Consumer Product Safety Commission that the G2

Filters had a defect in the form of filter failure which could create a substantial product hazard [or] created an unreasonable risk of serious injury or death.

52. Defendants did not inform the Consumer Product Safety Commission that the G2 Filters were defective as a result of filter failure and could create a substantial product hazard or created an unreasonable risk of serious injury or death.

53. At the time of the manufacturer and sale of the G2 Filter, Defendants knew or should have known that the G2 Filter:

(a) was designed and manufactured in such a manner so as to present an unreasonable risk of filter failure;

(b) was substandard and dangerous in that they were no electro-polished;

(c) was designed and manufactured as to present an unreasonable risk of fracture, perforation of vessels and organs, migration of the device and/or portions of the device; and /or

(d) was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body.

54. It was foreseeable that the G2 Filter was not of sufficient strength or structural integrity to withstand the foreseeable use of normal placement within the human body.

COUNT I
(Plaintiff v. C.R. Bard, Inc.)
(Negligence)

55. Plaintiff incorporates by reference each and every allegation set forth in paragraphs 1 through 54 herein.

56. Defendant C. R. Bard had a duty to exercise reasonable care in the design, manufacture, assembly, sale, distribution, installation, testing and inspection of the G2 Filter at the time it

placed it in the stream of commerce, including a duty to assure that the product did not cause users to suffer unnecessary injury.

57. Defendant C. R. Bard failed to exercise reasonable care in the design, manufacture, assembly, sale, distribution, installation, testing and inspection of the G2 Filter by placing it into the stream of commerce in that Defendant knew or should have known that the device was dangerous and defective due to filter failure, including fracture, migration and/or perforation/piercing of tissues, vessels and organs, and insufficient strength and structural integrity.

58. Defendant C.R. Bard was negligent and failed to exercise reasonable care in the design, manufacture, assembly, sale, distribution, installation, inspection and testing of the G2 Filter as follows:

(a) in failing to properly prepare the exterior surface of the G2 Filter prior to completion of the manufacturing process;

(b) in failing to properly prepare the exterior surface of the G2 Filter during the manufacturing process so as to eliminate “drawing marking”;

(c) in manufacturing the G2 Filter with “drawing markings”;

(d) in failing to design the G2 Filter to be able to withstand the normal anatomical and physiological loading cycles exerted in vivo;

(e) in failing to manufacture the G2 Filter to be able withstand the normal anatomical physiological loading cycles exerted in vivo;

(f) in failing to design the G2 Filter to prevent fracture of the device following insertion;

(g) in failing to properly manufacture the G2 Filter to prevent fracture of the device following insertion;

(h) in failing to design the G2 Filter to prevent perforation and/or piercing of the vascular lumen and/or other tissue, organs and vessels;

(i) in failing to properly manufacture the G2 Filter to prevent perforation and/or piercing of the vascular lumen and/or other tissue, organs and vessels;

(j) in failing to properly prepare the exterior surface of the G2 Filter during the manufacturing process so as to eliminate "circumferential grinding markings";

(k) in manufacturing the G2 Filter with "circumferential grinding markings";

(l) in failing to properly manufacture the G2 Filter to prevent failure following insertion;

(m) in failing to properly design the G2 Filter to prevent failure following insertion;

(n) in manufacturing the G2 Filter with cracks, flaws and gouges in the alloy which makes up the device;

(o) in manufacturing the G2 Filter with exterior defects such as cracks, flaws, gouges, "drawing markings" and "circumferential grinding markings" making the device more significantly susceptible to fatigue failure, fracture, piercing and perforation;

(p) in failing to electro-polish the exterior surfaces of the G2 Filter prior to the completion of the manufacturing process;

(q) in failing to properly electro-polish the G2 Filter prior to the completion of the manufacturing process;

(r) in failing to design the G2 Filter to include electro-polishing, including, but not limited to the exterior surfaces of the device;

(s) in failing to electro-polish the Nitinol material of the G2 Filter as part of the manufacturing process;

(t) in failing to design the G2 Filter to include electro-polishing of the Nitinol material of

the device;

(u) in failing to take those steps necessary during the manufacturing process to eliminate surface blemishes, drawing markings and circumferential grinding markings of the exterior surface of the device, including, but not limited to the Nitinol material utilized on the G2 Filter;

(v) in failing to design the G2 Filter in such a manner as to prevent an unreasonable risk of filter failure, including, but not limited to fracture, fatigue, migration and/or perforation/piercing of the lumen, vessels, tissues and organs;

(w) in failing to manufacture the G2 Filter in such a manner as to prevent an unreasonable risk of filter failure, including, but not limited fracture, fatigue, migration and/or perforation/piercing of the lumen, vessels, tissues and organs;

(x) in failing to design the G2 Filter so as to prevent an unreasonable risk of filter fracture, fatigue, perforation of vessels and/or organs, migration of the device and/or portions of the device;

(y) in failing to manufacture the G2 Filter so as to prevent an unreasonable risk of filter fracture, fatigue, perforation of vessels and/or organs, migration of the device and/or portions of the device;

(z) in designing the G2 Filter so as to have unreasonable and insufficient strength and/or structural integrity to withstand normal placement within the human body;

(aa) in manufacturing the G2 Filter so as to have unreasonable and insufficient strength and/or structural integrity to withstand normal placement within the human body;

(bb) in designing the G2 Filter so as to be insufficient to withstand the foreseeable use of placement in the human body;

(cc) in manufacturing the G2 Filter such that the exterior surface was inadequately, improperly and inappropriately prepared and/or finished, causing the device to weaken and fail leading to filter fracture, perforation of vessels and/or organs and migration of the device and/or portions of the device;

(dd) in designing the G2 Filter such that that exterior surface was inadequately, improperly and inappropriately prepared and/or finished causing the device to weaken and fail, leading to filter fracture, perforation or vessels and/or organs and migration of the device and/or portions of the device.

(ee) in failing to recall the G2 Filter in a timely and safe fashion;

(ff) in failing to notify and/or inform the Consumer Product Safety Commission that the G2 Filter that injured Plaintiff and which is the subject matter of this litigation contained a defect in the form of filter failure which could create a substantial product hazard or created an unreasonable risk of serious injury or death;

(gg) in failing to properly notify and/or warn of the dangers and risks of harm associated with the G2 Filter, namely, the incidence of filter failure, filter fracture, fatigue, perforation of vessels and/or organs and migration of the device and/or portions of the device;

(hh) in failing to properly warn Plaintiff, Physicians and the general public of the dangers and risks of harm associated with the G2 Filter, including, but not limited to filter failure, filter fracture, fatigue and perforation/piercing of vessels and organs;

(ii) in failing to properly warn Plaintiff, Physicians and the general public of the high incidence of filter failure, filter fracture, fatigue and perforation/ piercing of vessels and organs following insertions of the G2 Filter;

(jj) in failing to warn Plaintiff, Physicians and the general public that insertion of the G2 Filter placed patients at a "substantial" risk and/or danger of harm from filter failure, filter fracture, fatigue and perforation/piercing of vessels and organs;

(kk) in failing to properly warn of the dangers and risks of harm associated with the G2 Filter, namely, the high incidence of filter failure;

(ll) in failing to provide adequate warnings to apprise/notify Plaintiff, members of the medical community and the general public of the substantial hazards posed by the G2 Filters, including the significant and actual risk that the G2 Filters would fail and/or fracture resulting in injury, including, but not limited to the hemorrhage, damage, destruction and/or the perforation of tissues, vessels and organs;

(mm) in failing to provide adequate warnings to apprise/notify Plaintiff, members of the medical community and the general public of the actual incidence of failure of the Recovery Filter System and G2 Filter;

(nn) in failing to provide adequate warnings to apprise/notify Plaintiff, members of the medical community and the general public that the G2 Filter was not electro-polished; as was standard in the industry;

(oo) in failing to use ordinary care to manufacture the G2 Filter to be reasonably safe when put to its intended use;

(pp) in failing to use ordinary care to design the G2 Filter to be reasonably safe when put to its intended use;

(qq) in placing the G2 Filter into the stream of commerce when it knew or should have known of its dangerous condition;

(rr) in failing to warn and/or properly notify Plaintiff and users of the G2 Filter of the

unreasonably dangerous conditions existing on an within the G2 Filter including, but not limited to, filter failure and fatigue leading to migration, fracture and/or perforation/piercing of vessels, organs and tissues;

(ss) in failing to properly assemble the G2 Filter;

(tt) in failing to inform the Consumer Product Safety Commission that filter failures, fatigue fracture, migration and/or perforation of vessels associated with the G2 Filter created a substantial product hazard (or) created an unreasonable risk of serious injury or death;

(uu) in failing to adhere and/or follow the provisions of the Consumer Product Safety Act;

(vv) in failing to properly manufacture the G2 Filter;

(ww) in failing to properly design the G2 Filter; and

(xx) in manufacturing the G2 Filter so as to be insufficient to withstand the forseeable use of placement in the human body.

59. Defendant C.R. Bard knew or should have reasonably discovered the defects and/or unreasonably dangerous conditions existing on, in and within the G2 Filter prior to placing said device into the stream of commerce.

60. Defendant C.R. Bard knew or should have known that Plaintiff and users of the G2 Filter could foreseeably suffer injury as a result of Defendant's failure to exercise the ordinary and reasonable care described above. Defendant should have reasonably foreseen that Plaintiff and users of the G2 Filter would suffer serious injury or death as a result of filter fracture, fatigue migration and/or perforation/piercing of vessels and organs associated with Filter failure and as such should have designed the product to prevent such injuries of the type

sustained by Plaintiff.

61. At all times relevant hereto, Defendant C.R. Bard owed a duty to Plaintiff to properly manufacture, inspect, assemble, test and design the G2 Filter in order to make it safe for its intended use.

62. As a direct and proximate result of Defendant C.R. Bard's negligent acts and/or omissions, the G2 Filter was manufactured, sold and placed into the stream of commerce.

63. As a direct and proximate result of defendant C.R. Bard's negligent acts and/or omissions and the defective and unreasonably dangerous conditions of, on and within the G2 Filter, the G2 Filter placed within Plaintiff's body failed leading to fracture, fatigue, migration and/or perforation/piercing causing the filter to perforate, pierce and/or severely damage the Plaintiff's vessels, body, organs and tissues and/or not otherwise operate properly leading to severe physical injury.

64. As a direct and proximate result of Defendant C.R. Bard's negligent acts and/or omissions and the defective and unreasonably dangerous conditions of, on and within the G2 Filter, Plaintiff sustained serious physical injury as a result of Filter failure, including, but not limited to filter fracture, fatigue, migration and/or perforation/piercing of tissue, vessel and/or organs.

65. As a direct and proximate result of Defendant C.R. Bard's negligent acts and/or omissions and the defective and unreasonably dangerous conditions of, on and within the G2 Filter, Plaintiff sustained serious physical injuries, including, but not limited to, bilateral above-knee amputations, injury to his scrotum and other internal injuries requiring hospitalization and on-going medical care and treatment.

66. As a direct and proximate result of Defendant C.R. Bard's negligent acts and/or omissions

and the defective and unreasonably dangerous conditions of, on and within the G2 Filter, Plaintiff suffered and will in the future suffer emotional distress and/or other emotional, mental and/or psychological injuries requiring on-going psychological care and/or counseling.

67. As a direct and proximate result of Defendant C.R. Bard's negligent acts and/or omissions and the defective and unreasonably dangerous conditions of, on and within the G2 Filter, Plaintiff has suffered, and will in the future suffer, great pain and suffering, both mental and physical and incurred, and will in the future incur, expenses for medical care and treatment, housing, transportation, equipment and/or other facilities in an amount that is fair and reasonable.

68. As a direct and proximate result of Defendant C.R. Bard's negligent acts and/or omissions and the defective and unreasonably dangerous conditions of, on and within the G2 Filter, Plaintiff has suffered, and will in the future suffer a loss of income, and other economic damages in an amount that is fair and reasonable.

69. Defendant C.R. Bard's conduct was willful, wanton and malicious and showed a complete indifference to or conscious disregard for the safety of others, including Plaintiff, when it (1) continued to manufacture and place into the stream of commerce the G2 Filter with knowledge that said G2 Filter was defective and dangerous because of filter failure, including, filter fracture, fatigue, migration and perforation/piercing of vessels, organs and tissues; (2) took no steps to recall the G2 Filter from the market in a timely and safe manner; (3) failed to warn or inform Plaintiff, Physicians and the general public at large of those defects and dangers associated with the device and (4) made and continued to make false representations regard the safety and improvement of the device.

WHEREFORE, Plaintiff George Leus prays for judgment on Count I of his Complaint against Defendant C.R. Bard, Inc., for actual damages in an amount that is fair and reasonable, for punitive and/or exemplary damages in an amount that will serve to punish Defendant and to deter Defendant and others from like conduct, for his costs and expenses incurred herein, and for any other such relief the Court deems just and proper in the premises.

COUNT II
(Plaintiff v. C.R. Bard, Inc.)
(Strict Liability)

70. Plaintiff incorporates by reference each and every allegation set forth in paragraphs 1 through 54 herein.

71. Defendant C.R. Bard transferred and/or sold the G2 Filter in the normal course of business.

72. Plaintiff utilized the G2 Filter in the manner reasonably anticipated and Defendant should have reasonably foreseen that patients such as Plaintiff would suffer serious injury or death as a result of filter failure causing fracture, fatigue, migration and/or perforation/piercing of vessels, tissue and organs and Defendant should have designed the product (G2 Filter) so that injuries do not occur, including, but not limited to the type sustained by Plaintiff.

73. Defendant C.R. Bard placed into the stream of commerce the G2 Filter which is an unreasonably dangerous product.

74. The G2 Filter was then in a defective condition unreasonably dangerous when put to a reasonably anticipated use without knowledge of its characteristics when Defendant C.R. Bard sold the G2 Filter and/or placed it in the stream of commerce in that Defendant C.R. Bard:

(a) failed to properly prepare the exterior surface of the G2 Filter prior to completion of the

manufacturing process;

(b) failed to properly prepare the exterior surface of the G2 Filter during the manufacturing process so as to eliminate "drawing marking";

(c) manufactured the G2 Filter with "drawing markings";

(d) failed to design the G2 Filter to be able to withstand the normal anatomical and physiological loading cycles exerted in vivo;

(e) failed to manufacture the G2 Filter to be able withstand the normal anatomical and physiological loading cycles exerted in vivo;

(f) failed to design the G2 Filter to prevent fracture of the device following insertion;

(g) failed to properly manufacture the G2 Filter to prevent fracture of the device following insertion;

(h) failed to design the G2 Filter to prevent perforation and/or piercing of the vascular lumen and/or other tissue, organs and vessels;

(i) failed to properly manufacture the G2 Filter to prevent perforation and/or piercing of the vascular lumen and/or other tissue, organs and vessels;

(j) failed to properly prepare the exterior surface of the G2 Filter during the manufacturing process so as to eliminate "circumferential grinding markings";

(k) manufactured the G2 Filter with "circumferential grinding markings";

(l) failed to properly manufacture the G2 Filter to prevent failure following insertion;

(m) failed to properly design the G2 Filter to prevent failure following insertion;

(n) manufactured the G2 Filter with cracks, flaws and gouges in the alloy which makes up the device;

(o) manufactured the G2 Filter with exterior defects such as cracks, flaws, gouges, "drawing

markings" and "circumferential grinding markings" making the device more significantly susceptible to fatigue failure, fracture, piercing and perforation;

(p) failed to electro-polish the exterior surfaces of the G2 Filter prior to the completion of the manufacturing process;

(q) failed to properly electro-polish the G2 Filter prior to the completion of the manufacturing process;

(r) failed to design the G2 Filter to include electro-polishing, including, but not limited to the exterior surfaces of the device;

(s) failed to electro-polish the Nitinol material of the G2 Filter as part of the manufacturing process;

(t) failed to design the G2 Filter to include electro-polishing of the Nitinol material of the device;

(u) failed to take those steps necessary during the manufacturing process to eliminate surface blemishes, drawing markings and circumferential grinding markings of the exterior surface of the device, including, not limited to the Nitinol material utilized on the G2 Filter;

(v) failed to design the G2 Filter in such a manner as to prevent an unreasonable risk of filter failure, including, but not limited to fracture, fatigue, migration and/or perforation/piercing of the lumen, vessels, tissues and organs;

(w) failed to manufacture the G2 Filter in such a manner as to prevent an unreasonable risk of filter failure, including, but not limited fracture, fatigue, migration and/or perforation/piercing of the lumen, vessels, tissues and organs;

(x) failed to design the G2 Filter so as to prevent an unreasonable risk of filter fracture,

fatigue, perforation of vessels and/or organs, migration of the device and/or portions of the device;

(y) failed to manufacture the G2 Filter so as to prevent an unreasonable risk of filter fracture, fatigue, perforation of vessels and/or organs, migration of the device and/or portions of the device;

(z) designed the G2 Filter so as to have unreasonable and insufficient strength and/or structural integrity to withstand normal placement within the human body;

(aa) manufactured the G2 Filter so as to have unreasonable and insufficient strength and/or structural integrity to withstand normal placement within the human body;

(bb) designed the G2 Filter so as to be insufficient to withstand the foreseeable use of placement in the human body;

(cc) manufactured the G2 Filter such that the exterior surface was inadequately, improperly and inappropriately prepared and/or finished, causing the device to weaken and fail leading to filter fracture, perforation of vessels and/or organs and migration of the device and/or portions of the device;

(dd) designed the G2 Filter such that that exterior surface was inadequately improperly and inappropriately prepared and/or finished causing the device to weaken and fail, leading to filter fracture, perforation or vessels and/or organs and migration of the device and/or portions of the device.

(ee) failed to recall the G2 Filter in a timely and safe fashion;

(ff) failed to notify and/or inform the Consumer Product Safety Commission that the G2 Filter that injured Plaintiff and which is the subject matter of this litigation contained a defect in the form of filter failure which could create a substantial product hazard or

created an unreasonable risk of serious injury or death;

(gg) failed to properly notify and/or warn of the dangers and risks of harm associated with the G2 Filter, namely, the incidence of filter failure, filter fracture, fatigue, perforation of vessels and/or organs and migration of the device and/or portions of the device;

(hh) failed to properly warn Plaintiff, Physicians and the general public of the dangers and risks of harm associated with the G2 Filter, including, but not limited to filter failure, filter fracture, fatigue and perforation/piercing of vessels and organs;

(ii) failed to properly warn Plaintiff, Physicians and the general public of the high incidence of filter failure, filter fracture, fatigue and perforation/ piercing of vessels and organs following insertions of the G2 Filter;

(jj) failed to warn Plaintiff, Physicians and the general public that insertion of the G2 Filter placed patients at a "substantial" risk and/or danger of harm from filter failure, filter fracture, fatigue and perforation/piercing of vessels and organs;

(kk) failed to properly warn of the dangers and risks of harm associated with the G2 Filter, namely, the high incidence of filter failure;

(ll) failed to provide adequate warnings to apprise/notify Plaintiff, members of the medical community and the general public of the substantial hazards posed by the G2 Filters, including the significant and actual risk that the G2 Filters would fail and/or fracture resulting in injury, including but not limited, to the hemorrhage, damage, destruction and the perforation of tissues, vessels and organs;

(mm) failed to provide adequate warnings to apprise/notify Plaintiff, members of the medical community and the general public of the actual incidence of failure of the Recovery Filter System and G2 Filter;

(nn) failed to provide adequate warnings to apprise/notify Plaintiff, members of the medical community and the general public that the G2 Filter was not electro-polished; as was standard in the industry;

(oo) failed to use ordinary care to manufacture the G2 Filter to be reasonably safe when put to its intended use;

(pp) failed to use ordinary care to design the G2 Filter to be reasonably safe when put to its intended use;

(qq) placed the G2 Filter into the stream of commerce when it knew or should have known of its dangerous condition;

(rr) failed to warn and/or properly notify Plaintiff and users of the G2 Filter of the unreasonably dangerous conditions existing on an within the G2 Filter including, but not limited to, filter failure and fatigue leading to migration, fracture and/or perforation/piercing of vessels, organs and tissues;

(ss) failed to properly assemble the G2 Filter;

(tt) failed to inform the Consumer Product Safety Commission that filter failures, fracture, fatigue, migration and/or perforation of vessels associated with the G2 Filter, created a substantial product hazard (or) created an unreasonable risk of serious injury or death;

(uu) failed to adhere and/or follow the provisions of the Consumer Product Safety Act;

(vv) failed to properly manufacture the G2 Filter;

(ww) failed to properly design the G2 Filter; and

(xx) manufactured the G2 Filter so as to be insufficient to withstand the foreseeable use of placement in the human body.

75. The G2 Filter was in a defective condition and unreasonably dangerous when put to a

reasonably anticipated use and such defective condition existed when the product was sold and placed in the stream of commerce.

76. Plaintiff had no knowledge of the defective conditions existing in, on and within the G2 Filter and that said G2 Filter was dangerous.

77. Defendant C.R. Bard did not give Plaintiff adequate warning of said dangerous and defective conditions and adequate warning would have altered Plaintiff's actions.

78. At all times relevant hereto, Defendant C.R. Bard owed a duty to Plaintiff to properly manufacture, inspect, assemble, test and design the G2 Filter in order to make it safe for its intended use.

79. Defendant C.R. Bard knew or should have reasonably discovered the defects and/or unreasonably dangerous conditions existing on, in and within the G2 Filter prior to placing said device into the stream of commerce.

80. Defendant C.R. Bard knew or should have known that Plaintiff and users of the G2 Filter could foreseeably suffer injury as a result of Defendant's failure to exercise the ordinary and reasonable care described above. Defendant should have reasonably foreseen that Plaintiff and users of the G2 Filter would suffer serious injury or death as a result of filter fracture, fatigue, migration and/or perforation/piercing of vessels and organs associated with Filter failure and as such should have designed the product to prevent such injuries of the type sustained by Plaintiff.

81. As a direct and proximate result of Defendant C.R. Bard's negligent acts and/or omissions, the G2 Filter was manufactured, sold and placed into the stream of commerce.

82. As a direct and proximate result of the defective manufacture, design and/or defective condition of the G2 Filter existing at the time of sale and/or when placed in the stream of

commerce making it unreasonably dangerous when put to a reasonably anticipated use; and the sale of the G2 Filter without the above-described and/or adequate warnings, the G2 Filter placed within the Plaintiff's body failed leading to fracture, fatigue, migration and/or perforation/piercing causing the filter to perforate, pierce and/or severely damage Plaintiff's vessels, body, organs and tissues and/or not otherwise operate properly leading to severe physical injury.

83. As a direct and proximate result of the defective manufacture, design and/or defective condition of the G2 Filter existing at the time of sale and/or when placed in the stream of commerce making it unreasonably dangerous when put to a reasonably anticipated use; and the sale of the G2 Filter without the above-described and/or adequate warnings, Plaintiff sustained serious physical injury as a result of Filter failure, including, but no limited to filter fracture, fatigue, migration and/or perforation/piercing of tissue, vessel and/or organs.

84. As a direct and proximate result of the defective manufacture, design and/or defective condition of the G2 Filter existing at the time of sale and/or when placed in the stream of commerce making it unreasonably dangerous when put to a reasonably anticipated use; and the sale of the G2 Filter without the above-described and/or adequate warnings, Plaintiff sustained serious physical injuries, including, but not limited to, bilateral above-knee amputations, injury to his scrotum and other internal injuries requiring hospitalization and on-going medical care and treatment.

85. As a direct and proximate result of the defective manufacture, design and/or defective condition of the G2 Filter existing at the time of sale and/or when placed in the stream of commerce making it unreasonably dangerous when put to a reasonably anticipated use; and the sale of the G2 Filter without the above-described and/or adequate warnings, Plaintiff

suffered and will in the future suffer emotional distress and/or other emotional, mental and/or psychological injuries requiring on-going psychological care and/or counseling.

86. As a direct and proximate result of the defective manufacture, design and/or defective condition of the G2 Filter existing at the time of sale and/or when placed in the stream of commerce making it unreasonably dangerous when put to a reasonably anticipated use; and the sale of the G2 Filter without the above-described and/or adequate warnings, Plaintiff has suffered, and will in the future suffer, great pain and suffering, both mental and physical and incurred, and will in the future incur, expenses for medical care and treatment, housing, transportation, equipment, and/or other facilities in an amount that is fair and reasonable.

87. As a direct and proximate result of the defective manufacture, design and/or defective condition of the G2 Filter existing at the time of sale and/or when placed in the stream of commerce making it unreasonably dangerous when put to a reasonably anticipated use; and the sale of the G2 Filter without the above-described and/or adequate warnings, Plaintiff has suffered, and will in the future suffer a loss of income, and other economic damages in an amount that is fair and reasonable.

88. Defendant C.R. Bard's conduct was willful, wanton and malicious and showed a complete indifference to or conscious disregard for the safety of others, including Plaintiff, when it (1) continued to manufacture and place into the stream of commerce the G2 Filter with knowledge that said G2 Filter was defective and dangerous because of filter failure, including, filter fracture, fatigue, migration and perforation/piercing of vessels, organs and tissues; (2) took no steps to recall the G2 Filter from the market in a timely and safe manner; (3) failed to warn or inform Plaintiff, Physicians and the general public at large of those defects and dangers associated with the device and (4) made and continued to make false

representations regard the safety and improvement of the device.

WHEREFORE, Plaintiff George Leus prays for judgment on Count II of his Complaint against Defendant C.R. Bard, Inc., for actual damages in on amount that is fair and reasonable, for punitive and/or exemplary damages in an amount that will serve to punish Defendant and to deter Defendant and others from like conduct, for his costs and expenses incurred herein, and for any other such relief the Court deems just and proper in the premises.

COUNT III
(Plaintiff v. C.R. Bard, Inc.)
(Breach of Implied Warranty)

89. Plaintiff incorporates by reference each and every allegation set forth in paragraphs 1 through 54 herein.

90. Defendant C.R. Bard was in the business of designing, developing, manufacturing, marketing and selling sophisticated medical devices, including the G2 Filter.

91. Defendant C.R. Bard knew or should have known that the members of the general public, including Plaintiff, relied upon its skill and judgment to properly design, assemble, manufacture, test and inspect the G2 Filter.

92. At the time Defendant C. R. Bard designed, manufactured, assembled, distributed and sold the G2 Filter it knew of the use for which it was intended and implied and warranted that the G2 Filter was of merchantable quality and safe for its intended use.

93. At the time Defendant C. R. Bard designed, manufactured, produced, tested, studied, inspected, marketed, advertised, sold, promoted and/or distributed the G2 Filter for use by Plaintiff, it knew (1) of the potential for fracture, perforation of vessels, migration or other potential failures, and (2) they were manufactured in such a manner so that the exterior surface of the G2 Filter was inadequately prepared and/or finished thereby subjecting the

device to weakening and failure.

94. Plaintiff reasonably relied upon the skill and judgment of Defendant C.R. Bard as to whether the G2 Filter was of merchantable quality and safe and fit for its intended use. Plaintiff had no knowledge that the G2 Filter was not safe and fit for its intended use.

95. Plaintiff and Defendant C.R. Bard, Inc. were in privity of contract.

96. The G2 Filter was used in a manner in which it was intended to be used.

97. Contrary to such implied warranty, Defendant C.R. Bard's G2 Filter was not of merchantable quality, safe or fit for its intended use as described herein above because they were and are defective, failed to function as safely as an ordinary user would expect when used in an intended and reasonably foreseeable manner, and because they presented a substantial likelihood of failure, fracture, fatigue, migration and/or perforation of vessels.

98. Contrary to such implied warranty, the G2 Filter was not of merchantable quality or safe for its intended use because they were designed and manufacture in such a manner so that the exterior surface of the G2 Filter was inadequately, improperly and inappropriately prepared and/or finished, thereby subjecting the device to weakening and failure.

99. Defendant C.R. Bard was a merchant with respect to the G2 Filter which was sold to Plaintiff and/or his representative and there was an implied warranty that the G2 Filter was merchantable.

100. Defendant C.R. Bard breached the implied warranty in the contract for the sale of goods in that the G2 Filter was not fit for its intended purpose. Furthermore, the G2 Filter did not conform to the promises, representations or affirmations made by Defendant regarding the product.

101. As a direct and proximate result of Defendant C.R. Bard's breach of implied warranty, the

G2 Filter placed within Plaintiff's body failed leading to fracture, fatigue, migration and/or perforation/piercing causing the filter to perforate, pierce and/or severely damage the Plaintiff's vessels, body, organs and tissues and/or not otherwise operate properly leading to severe physical injury.

102. As a direct and proximate result of Defendant C.R. Bard's breach of implied warranty, Plaintiff sustained serious physical injury as a result of Filter failure, including, but not limited to filter fracture, fatigue, migration and/or perforation/piercing of tissue, vessel and/or organs.

103. As a direct and proximate result of Defendant C.R. Bard's breach of implied warranty, Plaintiff sustained serious physical injuries, including, but not limited to, bilateral above-knee amputations, injury to his scrotum and other internal injuries requiring hospitalization and on-going medical care and treatment.

104. As a direct and proximate result of Defendant C.R. Bard's breach of implied warranty, Plaintiff suffered and will in the future suffer emotional distress and/or other emotional, mental and/or psychological injuries requiring on-going psychological care and/or counseling.

105. As a direct and proximate result of Defendant C.R. Bard's breach of implied warranty, Plaintiff has suffered, and will in the future suffer, great pain and suffering, both mental and physical and incurred, and will in the future incur, expenses for medical care and treatment, housing, transportation, equipment and/or other facilities in an amount that is fair and reasonable.

106. As a direct and proximate result of Defendant C.R. Bard's breach of implied warranty, Plaintiff has suffered, and will in the future suffer a loss of income, and other economic

damages in an amount that is fair and reasonable.

107. Defendant C.R. Bard's conduct was willful, wanton and malicious and showed a complete indifference to or conscious disregard for the safety of others including Plaintiff, when it (1) continued to manufacture and place into the stream of commerce the G2 Filter with knowledge that said G2 Filter was defective and dangerous because of filter failure, including, filter fracture, fatigue, migration and perforation/piercing of vessels, organs and tissues; (2) took no steps to recall the G2 Filter from the market in a timely and safe manner; (3) failed to warn or inform Plaintiff, Physicians and the general public at large of those defects and dangers associated with the device and (4) made and continued to make false representations regard the safety and improvement of the device.

WHEREFORE, Plaintiff George Leus prays for judgment on Count III of his Complaint against Defendant C.R. Bard, Inc., for actual damages in on amount that is fair and reasonable, for punitive and/or exemplary damages in an amount that will serve to punish Defendant and to deter Defendant and others from like conduct, for his costs and expenses incurred herein, and for any other such relief the Court deems just and proper in the premises.

COUNT IV
(Plaintiff v. C.R. Bard, Inc.)
(Fraudulent Concealment)

108. Plaintiff incorporates by reference each and every allegation set forth in paragraphs 1 through 54 herein.

109. At all times relevant hereto, Defendant C.R. Bard was in the business of designing, developing, manufacturing, marketing and selling sophisticated medical devices, including the G2 Filter.

110. Defendant C.R. Bard's G2 Filter was defectively manufactured and designed, such that it

posed a substantial risk of failure, including fracture, fatigue, migration and perforation/piercing of vessels and organs and serious injury or death.

111. Defendant C.R. Bard was aware of the defective nature of the G2 Filter and the risks and dangers associated therewith.

112. As the manufacturer, distributor, marketer and seller of sophisticated medical devices, including the G2 Filter, Defendant C.R. Bard had a legal duty to fully disclose the hazards of its product to Plaintiff, the public at large and the medical community.

113. Defendant C.R. Bard also owed a duty to disclose the hazardous nature of their G2 Filter to Plaintiff, the public at large and the medical community, because Defendant alone had knowledge of material facts, namely the hazardous nature of the G2 Filter which were not accessible to Plaintiffs, the public at the large and the medical community.

114. Defendant C.R. Bard also owed a duty to disclose the hazardous nature of the G2 Filter to Plaintiff, the public at large and the medical community because Defendants made representations regarding the G2 Filter, but failed to disclose additional facts materially qualify the facts disclosed and/or which rendered the disclosures made likely to mislead Plaintiff, the public at large and the medical community.

115. Notwithstanding their knowledge of the hazardous nature of the G2 Filter, Defendant C.R. Bard, at all material times hereto, concealed said hazards from Plaintiff, the public at large and the medical community, so that these groups or individuals would use or authorize use of the G2 Filter.

116. Plaintiff, the public at large and the medical community were unaware of the hazards of the G2 Filter and would not have acted as they did had they known of said hazards.

117. As a direct and proximate result of Defendant C.R. Bard's fraudulent concealment of the

hazards of the G2 Filter from Plaintiff, the public at large and the medical community, Defendant's G2 Filter was implanted in Plaintiff.

118. As a direct and proximate result of Defendant C.R. Bard's fraudulent concealment of the hazards of the G2 Filter from Plaintiff, the public at large and the medical community, the G2 Filter placed within Plaintiff's body failed leading to fracture, fatigue, migration and/or perforation/piercing causing the filter to perforate, pierce and/or severely damage the Plaintiff's vessels, body, organs and tissues and/or not otherwise operate properly leading to severe physical injury.

119. Defendant C.R. Bard's representation that its G2 Filter were safe for use, of sufficient strength and integrity and properly designed and manufactured were false and said representations were material in regards to the safety of the product and the use of said product by Plaintiff, the general public and the medical profession.

120. Defendant C.R. Bard knew that said representations were false.

121. Defendant C.R. Bard intended that the general public, the medical profession and Plaintiff rely and act upon on said representations and purchase, use and recommend the use of said product and that said actions in reliance upon said representations was reasonably contemplated.

122. Plaintiff, the general public and the medical profession were ignorant of the falsity of said representations and relied on said representations as being true.

123. Plaintiff, the general public and the medical profession had a right to and did rely upon said representations.

124. Plaintiff was injured as a direct and proximate result of said false representations made by defendant C.R. Bard.

125. As a direct and proximate result of Defendant C.R. Bard's false representations and fraudulent concealment of the hazards of the G2 Filter from Plaintiff, the public at large and the medical community, Plaintiff sustained serious physical injury as a result of Filter failure, including, but not limited to filter fracture, fatigue, migration and/or perforation/piercing of tissue, vessel and/or organs.

126. As a direct and proximate result of Defendant C.R. Bard's false representations and fraudulent concealment of the hazards of the G2 Filter from Plaintiff, the public at large and the medical community, Plaintiff sustained serious physical injuries, including, but not limited to, bilateral above-knee amputations, injury to his scrotum and other internal injuries requiring hospitalization and on-going medical care and treatment.

127. As a direct and proximate result of Defendant C.R. Bard's false representations and fraudulent concealment of the hazards of the G2 Filter from Plaintiff, the public at large and the medical community, Plaintiff suffered and will in the future suffer emotional distress and/or other emotional, mental and/or psychological injuries requiring on-going psychological care and/or counseling.

128. As a direct and proximate result of Defendant C.R. Bard's false representations and fraudulent concealment of the hazards of the G2 Filter from Plaintiff, the public at large and the medical community, Plaintiff has suffered, and will in the future suffer, great pain and suffering, both mental and physical and incurred, and will in the future incur, expenses for medical care and treatment, housing, transportation, equipment and/or other facilities in an amount that is fair and reasonable.

129. As a direct and proximate result of Defendant C.R. Bard's false representations and fraudulent concealment of the hazards of the G2 Filter from Plaintiff, the public at large and

the medical community, Plaintiff has suffered, and will in the future suffer a loss of income, and other economic damages in an amount that is fair and reasonable.

130. Defendant C.R. Bard's conduct was willful, wanton and malicious and showed a complete indifference to or conscious disregard for the safety of others, including Plaintiff, when it (1) continued to manufacture and place into the stream of commerce the G2 Filter with knowledge that said G2 Filter was defective and dangerous because of filter failure, including, filter fracture, fatigue, migration and perforation/piercing of vessels, organs and tissues; (2) took no steps to recall the G2 Filter from the market in a timely and safe manner; (3) failed to warn or inform Plaintiff, Physicians and the general public at large of those defects and dangers associated with the device and (4) made and continued to make false representations regard the safety and improvement of the device.

WHEREFORE, Plaintiff George Leus prays for judgment on Count IV of his Complaint against Defendant C.R. Bard, Inc., for actual damages in on amount that is fair and reasonable, for punitive and/or exemplary damages in an amount that will serve to punish Defendant and to deter Defendant and others from like conduct, for his costs and expenses incurred herein, and for any other such relief the Court deems just and proper in the premises.

COUNT V
(Plaintiff v. Bard Peripheral Vascular, Inc.)
(Negligence)

131. Plaintiff incorporates by reference each and every allegation set forth in paragraphs 1 through 54 herein.

132. Defendant Bard Peripheral had a duty to exercise reasonable care in the design, manufacture, assembly, sale, distribution, installation, testing and inspection of the G2 Filter at the time it placed it in the stream of commerce, including a duty to assure that the product

did not cause users to suffer unnecessary injury.

133. Defendant Bard Peripheral failed to exercise reasonable care in the design, manufacture, assembly, sale, distribution, installation, testing and inspection of the G2 Filter by placing it into the stream of commerce in that Defendant knew or should have known that the device was dangerous and defective due to filter failure, including fracture, migration and/or perforation/piercing of tissues, vessels and organs, and insufficient strength and structural integrity.

134. Defendant Bard Peripheral was negligent and failed to exercise reasonable care in the design, manufacture, assembly, sale, distribution, installation, inspection and testing of the G2 Filter as follows:

(a) in failing to properly prepare the exterior surface of the G2 Filter prior to completion of the manufacturing process;

(b) in failing to properly prepare the exterior surface of the G2 Filter during the manufacturing process so as to eliminate “drawing marking”;

(c) in manufacturing the G2 Filter with “drawing markings”;

(d) in failing to design the G2 Filter to be able to withstand the normal anatomical and physiological loading cycles exerted in vivo;

(e) in failing to manufacture the G2 Filter to be able withstand the normal anatomical physiological loading cycles exerted in vivo;

(f) in failing to design the G2 Filter to prevent fracture of the device following insertion;

(g) in failing to properly manufacture the G2 Filter to prevent fracture of the device following insertion;

(h) in failing to design the G2 Filter to prevent perforation and/or piercing of the vascular

lumen and/or other tissue, organs and vessels;

(i) in failing to properly manufacture the G2 Filter to prevent perforation and/or piercing of the vascular lumen and/or other tissue, organs and vessels;

(j) in failing to properly prepare the exterior surface of the G2 Filter during the manufacturing process so as to eliminate "circumferential grinding markings";

(k) in manufacturing the G2 Filter with "circumferential grinding markings";

(l) in failing to properly manufacture the G2 Filter to prevent failure following insertion;

(m) in failing to properly design the G2 Filter to prevent failure following insertion;

(n) in manufacturing the G2 Filter with cracks, flaws and gouges in the alloy which makes up the device;

(o) in manufacturing the G2 Filter with exterior defects such as cracks, flaws, gouges, "drawing markings" and "circumferential grinding markings" making the device more significantly susceptible to fatigue failure, fracture, piercing and perforation;

(p) in failing to electro-polish the exterior surfaces of the G2 Filter prior to the completion of the manufacturing process;

(q) in failing to properly electro-polish the G2 Filter prior to the completion of the manufacturing process;

(r) in failing to design the G2 Filter to include electro-polishing, including, but not limited to the exterior surfaces of the device;

(s) in failing to electro-polish the Nitinol material of the G2 Filter as part of the manufacturing process;

(t) in failing to design the G2 Filter to include electro-polishing of the Nitinol material of the device;

(u) in failing to take those steps necessary during the manufacturing process to eliminate surface blemishes, drawing markings and circumferential grinding markings of the exterior surface of the device, including, but not limited to the Nitinol material utilized on the G2 Filter;

(v) in failing to design the G2 Filter in such a manner as to prevent an unreasonable risk of filter failure, including, but not limited to fracture, fatigue, migration and/or perforation/piercing of the lumen, vessels, tissues and organs;

(w) in failing to manufacture the G2 Filter in such a manner as to prevent an unreasonable risk of filter failure, including, but not limited fracture, fatigue, migration and/or perforation/piercing of the lumen, vessels, tissues and organs;

(x) in failing to design the G2 Filter so as to prevent an unreasonable risk of filter fracture, fatigue, perforation of vessels and/or organs, migration of the device and/or portions of the device;

(y) in failing to manufacture the G2 Filter so as to prevent an unreasonable risk of filter fracture, fatigue, perforation of vessels and/or organs, migration of the device and/or portions of the device;

(z) in designing the G2 Filter so as to have unreasonable and insufficient strength and/or structural integrity to withstand normal placement within the human body;

(aa) in manufacturing the G2 Filter so as to have unreasonable and insufficient strength and/or structural integrity to withstand normal placement within the human body;

(bb) in designing the G2 Filter so as to be insufficient to withstand the foreseeable use of placement in the human body;

(cc) in manufacturing the G2 Filter such that the exterior surface was inadequately,

improperly and inappropriately prepared and/or finished, causing the device to weaken and fail leading to filter fracture, perforation of vessels and/or organs and migration of the device and/or portions of the device;

(dd) in designing the G2 Filter such that that exterior surface was inadequately, improperly and inappropriately prepared and/or finished causing the device to weaken and fail, leading to filter fracture, perforation or vessels and/or organs and migration of the device and/or portions of the device.

(ee) in failing to recall the G2 Filter in a timely and safe fashion;

(ff) in failing to notify and/or inform the Consumer Product Safety Commission that the G2 Filter that injured Plaintiff and which is the subject matter of this litigation contained a defect in the form of filter failure which could create a substantial product hazard or created an unreasonable risk of serious injury or death;

(gg) in failing to properly notify and/or warn of the dangers and risks of harm associated with the G2 Filter, namely, the incidence of filter failure, filter fracture, fatigue, perforation of vessels and/or organs and migration of the device and/or portions of the device;

(hh) in failing to properly warn Plaintiff, Physicians and the general public of the dangers and risks of harm associated with the G2 Filter, including, but not limited to filter failure, filter fracture, fatigue and perforation/piercing of vessels and organs;

(ii) in failing to properly warn Plaintiff, Physicians and the general public of the high incidence of filter failure, filter fracture, fatigue and perforation/ piercing of vessels and organs following insertions of the G2 Filter;

(jj) in failing to warn Plaintiff, Physicians and the general public that insertion of the G2

Filter placed patients at a “substantial” risk and/or danger of harm from filter failure, filter fracture, fatigue and perforation/piercing of vessels and organs;

(kk) in failing to properly warn of the dangers and risks of harm associated with the G2 Filter, namely, the high incidence of filter failure;

(ll) in failing to provide adequate warnings to apprise/notify Plaintiff, members of the medical community and the general public of the substantial hazards posed by the G2 Filters, including the significant and actual risk that the G2 Filters would fail and/or fracture resulting in injury, including, but not limited to the hemorrhage, damage, destruction and/or the perforation of tissues, vessels and organs;

(mm) in failing to provide adequate warnings to apprise/notify Plaintiff, members of the medical community and the general public of the actual incidence of failure of the Recovery Filter System and G2 Filter;

(nn) in failing to provide adequate warnings to apprise/notify Plaintiff, members of the medical community and the general public that the G2 Filter was not electro-polished; as was standard in the industry;

(oo) in failing to use ordinary care to manufacture the G2 Filter to be reasonably safe when put to its intended use;

(pp) in failing to use ordinary care to design the G2 Filter to be reasonably safe when put to its intended use;

(qq) in placing the G2 Filter into the stream of commerce when it knew or should have known of its dangerous condition;

(rr) in failing to warn and/or properly notify Plaintiff and users of the G2 Filter of the unreasonably dangerous conditions existing on an within the G2 Filter including, but not

limited to, filter failure and fatigue leading to migration, fracture and/or perforation/piercing of vessels, organs and tissues;

(ss) in failing to properly assemble the G2 Filter;

(tt) in failing to inform the Consumer Product Safety Commission that filter failures, fatigue fracture, migration and/or perforation of vessels associated with the G2 Filter created a substantial product hazard (or) created an unreasonable risk of serious injury or death;

(uu) in failing to adhere and/or follow the provisions of the Consumer Product Safety Act;

(vv) in failing to properly manufacture the G2 Filter;

(ww) in failing to properly design the G2 Filter; and

(xx) in manufacturing the G2 Filter so as to be insufficient to withstand the forseeable use of placement in the human body.

135. Defendant Bard Peripheral knew or should have reasonably discovered the defects and/or unreasonably dangerous conditions existing on, in and within the G2 Filter prior to placing said device into the stream of commerce.

136. Defendant C.R. Bard knew or should have known that Plaintiff and users of the G2 Filter could foreseeably suffer injury as a result of Defendant's failure to exercise the ordinary and reasonable care described above. Defendant should have reasonably foreseen that Plaintiff and users of the G2 Filter would suffer serious injury or death as a result of filter fracture, fatigue migration and/or perforation/piercing of vessels and organs associated with Filter failure and as such should have designed the product to prevent such injuries of the type sustained by Plaintiff.

137. At all times relevant hereto, Defendant Bard Peripheral owed a duty to Plaintiff to properly manufacture, inspect, assemble, test and design the G2 Filter in order to make it safe for its intended use.

138. As a direct and proximate result of Defendant Bard Peripheral's negligent acts and/or omissions, the G2 Filter was manufactured, sold and placed into the stream of commerce.

139. As a direct and proximate result of defendant Bard Peripheral's negligent acts and/or omissions and the defective and unreasonably dangerous conditions of, on and within the G2 Filter, the G2 Filter placed within Plaintiff's body failed leading to fracture, fatigue, migration and/or perforation/piercing causing the filter to perforate, pierce and/or severely damage the Plaintiff's vessels, body, organs and tissues and/or not otherwise operate properly leading to severe physical injury.

140. As a direct and proximate result of Defendant Bard Peripheral's negligent acts and/or omissions and the defective and unreasonably dangerous conditions of, on and within the G2 Filter, Plaintiff sustained serious physical injury as a result of Filter failure, including, but not limited to filter fracture, fatigue, migration and/or perforation/piercing of tissue, vessel and/or organs.

141. As a direct and proximate result of Defendant Bard Peripheral's negligent acts and/or omissions and the defective and unreasonably dangerous conditions of, on and within the G2 Filter, Plaintiff sustained serious physical injuries, including, but not limited to, bilateral above-knee amputations, injury to his scrotum and other internal injuries requiring hospitalization and on-going medical care and treatment.

142. As a direct and proximate result of Defendant Bard Peripheral's negligent acts and/or omissions and the defective and unreasonably dangerous conditions of, on and within the G2

Filter, Plaintiff suffered and will in the future suffer emotional distress and/or other emotional, mental and/or psychological injuries requiring on-going psychological care and/or counseling.

143. As a direct and proximate result of Defendant Bard Peripheral's negligent acts and/or omissions and the defective and unreasonably dangerous conditions of, on and within the G2 Filter, Plaintiff has suffered, and will in the future suffer, great pain and suffering, both mental and physical and incurred, and will in the future incur, expenses for medical care and treatment, housing, transportation, equipment and/or other facilities in an amount that is fair and reasonable.

144. As a direct and proximate result of Defendant Bard Peripheral's negligent acts and/or omissions and the defective and unreasonably dangerous conditions of, on and within the G2 Filter, Plaintiff has suffered, and will in the future suffer a loss of income, and other economic damages in an amount that is fair and reasonable.

145. Defendant Bard Peripheral's conduct was willful, wanton and malicious and showed a complete indifference to or conscious disregard for the safety of others, including Plaintiff, when it (1) continued to manufacture and place into the stream of commerce the G2 Filter with knowledge that said G2 Filter was defective and dangerous because of filter failure, including, filter fracture, fatigue, migration and perforation/piercing of vessels, organs and tissues; (2) took no steps to recall the G2 Filter from the market in a timely and safe manner; (3) failed to warn or inform Plaintiff, Physicians and the general public at large of those defects and dangers associated with the device and (4) made and continued to make false representations regard the safety and improvement of the device.

WHEREFORE, Plaintiff George Leus prays for judgment on Count V of his Complaint against Defendant Bard Peripheral Vascular, Inc., for actual damages in an amount that is fair and reasonable, for punitive and/or exemplary damages in an amount that will serve to punish Defendant and to deter Defendant and others from like conduct, for his costs and expenses incurred herein, and for any other such relief the Court deems just and proper in the premises.

COUNT VI
(Plaintiff v. Bard Peripheral Vascular, Inc.)
(Strict Liability)

146. Plaintiff incorporates by reference each and every allegation set forth in paragraphs 1 through 54 herein.

147. Defendant Bard Peripheral transferred and/or sold the G2 Filter in the normal course of business.

148. Plaintiff utilized the G2 Filter in the manner reasonably anticipated and Defendant should have reasonably foreseen that patients such as Plaintiff would suffer serious injury or death as a result of filter failure causing fracture, fatigue, migration and/or perforation/piercing of vessels, tissue and organs and Defendant should have designed the product (G2 Filter) so that injuries do not occur, including, but not limited to the type sustained by Plaintiff.

149. Defendant Bard Peripheral placed into the stream of commerce the G2 Filter which is an unreasonably dangerous product.

150. The G2 Filter was then in a defective condition unreasonably dangerous when put to a reasonably anticipated use without knowledge of its characteristics when Defendant Bard Peripheral sold the G2 Filter and/or placed it in the stream of commerce in that Defendant Bard Peripheral:

(a) failed to properly prepare the exterior surface of the G2 Filter prior to completion of the

manufacturing process;

(b) failed to properly prepare the exterior surface of the G2 Filter during the manufacturing process so as to eliminate "drawing marking";

(c) manufactured the G2 Filter with "drawing markings";

(d) failed to design the G2 Filter to be able to withstand the normal anatomical and physiological loading cycles exerted in vivo;

(e) failed to manufacture the G2 Filter to be able withstand the normal anatomical and physiological loading cycles exerted in vivo;

(f) failed to design the G2 Filter to prevent fracture of the device following insertion;

(g) failed to properly manufacture the G2 Filter to prevent fracture of the device following insertion;

(h) failed to design the G2 Filter to prevent perforation and/or piercing of the vascular lumen and/or other tissue, organs and vessels;

(i) failed to properly manufacture the G2 Filter to prevent perforation and/or piercing of the vascular lumen and/or other tissue, organs and vessels;

(j) failed to properly prepare the exterior surface of the G2 Filter during the manufacturing process so as to eliminate "circumferential grinding markings";

(k) manufactured the G2 Filter with "circumferential grinding markings";

(l) failed to properly manufacture the G2 Filter to prevent failure following insertion;

(m) failed to properly design the G2 Filter to prevent failure following insertion;

(n) manufactured the G2 Filter with cracks, flaws and gouges in the alloy which makes up the device;

(o) manufactured the G2 Filter with exterior defects such as cracks, flaws, gouges, "drawing

markings" and "circumferential grinding markings" making the device more significantly susceptible to fatigue failure, fracture, piercing and perforation;

(p) failed to electro-polish the exterior surfaces of the G2 Filter prior to the completion of the manufacturing process;

(q) failed to properly electro-polish the G2 Filter prior to the completion of the manufacturing process;

(r) failed to design the G2 Filter to include electro-polishing, including, but not limited to the exterior surfaces of the device;

(s) failed to electro-polish the Nitinol material of the G2 Filter as part of the manufacturing process;

(t) failed to design the G2 Filter to include electro-polishing of the Nitinol material of the device;

(u) failed to take those steps necessary during the manufacturing process to eliminate surface blemishes, drawing markings and circumferential grinding markings of the exterior surface of the device, including, not limited to the Nitinol material utilized on the G2 Filter;

(v) failed to design the G2 Filter in such a manner as to prevent an unreasonable risk of filter failure, including, but not limited to fracture, fatigue, migration and/or perforation/piercing of the lumen, vessels, tissues and organs;

(w) failed to manufacture the G2 Filter in such a manner as to prevent an unreasonable risk of filter failure, including, but not limited fracture, fatigue, migration and/or perforation/piercing of the lumen, vessels, tissues and organs;

(x) failed to design the G2 Filter so as to prevent an unreasonable risk of filter fracture,

fatigue, perforation of vessels and/or organs, migration of the device and/or portions of the device;

(y) failed to manufacture the G2 Filter so as to prevent an unreasonable risk of filter fracture, fatigue, perforation of vessels and/or organs, migration of the device and/or portions of the device;

(z) designed the G2 Filter so as to have unreasonable and insufficient strength and/or structural integrity to withstand normal placement within the human body;

(aa) manufactured the G2 Filter so as to have unreasonable and insufficient strength and/or structural integrity to withstand normal placement within the human body;

(bb) designed the G2 Filter so as to be insufficient to withstand the foreseeable use of placement in the human body;

(cc) manufactured the G2 Filter such that the exterior surface was inadequately, improperly and inappropriately prepared and/or finished, causing the device to weaken and fail leading to filter fracture, perforation of vessels and/or organs and migration of the device and/or portions of the device;

(dd) designed the G2 Filter such that that exterior surface was inadequately improperly and inappropriately prepared and/or finished causing the device to weaken and fail, leading to filter fracture, perforation or vessels and/or organs and migration of the device and/or portions of the device.

(ee) failed to recall the G2 Filter in a timely and safe fashion;

(ff) failed to notify and/or inform the Consumer Product Safety Commission that the G2 Filter that injured Plaintiff and which is the subject matter of this litigation contained a defect in the form of filter failure which could create a substantial product hazard or

created an unreasonable risk of serious injury or death;

(gg) failed to properly notify and/or warn of the dangers and risks of harm associated with the G2 Filter, namely, the incidence of filter failure, filter fracture, fatigue, perforation of vessels and/or organs and migration of the device and/or portions of the device;

(hh) failed to properly warn Plaintiff, Physicians and the general public of the dangers and risks of harm associated with the G2 Filter, including, but not limited to filter failure, filter fracture, fatigue and perforation/piercing of vessels and organs;

(ii) failed to properly warn Plaintiff, Physicians and the general public of the high incidence of filter failure, filter fracture, fatigue and perforation/ piercing of vessels and organs following insertions of the G2 Filter;

(jj) failed to warn Plaintiff, Physicians and the general public that insertion of the G2 Filter placed patients at a "substantial" risk and/or danger of harm from filter failure, filter fracture, fatigue and perforation/piercing of vessels and organs;

(kk) failed to properly warn of the dangers and risks of harm associated with the G2 Filter, namely, the high incidence of filter failure;

(ll) failed to provide adequate warnings to apprise/notify Plaintiff, members of the medical community and the general public of the substantial hazards posed by the G2 Filters, including the significant and actual risk that the G2 Filters would fail and/or fracture resulting in injury, including but not limited, to the hemorrhage, damage, destruction and the perforation of tissues, vessels and organs;

(mm) failed to provide adequate warnings to apprise/notify Plaintiff, members of the medical community and the general public of the actual incidence of failure of the Recovery Filter System and G2 Filter;

(nn) failed to provide adequate warnings to apprise/notify Plaintiff, members of the medical community and the general public that the G2 Filter was not electro-polished; as was standard in the industry;

(oo) failed to use ordinary care to manufacture the G2 Filter to be reasonably safe when put to its intended use;

(pp) failed to use ordinary care to design the G2 Filter to be reasonably safe when put to its intended use;

(qq) placed the G2 Filter into the stream of commerce when it knew or should have known of its dangerous condition;

(rr) failed to warn and/or properly notify Plaintiff and users of the G2 Filter of the unreasonably dangerous conditions existing on an within the G2 Filter including, but not limited to, filter failure and fatigue leading to migration, fracture and/or perforation/piercing of vessels, organs and tissues;

(ss) failed to properly assemble the G2 Filter;

(tt) failed to inform the Consumer Product Safety Commission that filter failures, fracture, fatigue, migration and/or perforation of vessels associated with the G2 Filter, created a substantial product hazard (or) created an unreasonable risk of serious injury or death;

(uu) failed to adhere and/or follow the provisions of the Consumer Product Safety Act;

(vv) failed to properly manufacture the G2 Filter;

(ww) failed to properly design the G2 Filter; and

(xx) manufactured the G2 Filter so as to be insufficient to withstand the foreseeable use of placement in the human body.

151. The G2 Filter was in a defective condition and unreasonably dangerous when put to a

reasonably anticipated use and such defective condition existed when the product was sold and placed in the stream of commerce.

152. Plaintiff had no knowledge of the defective conditions existing in, on and within the G2 Filter and that said G2 Filter was dangerous.

153. Defendant Bard Peripheral did not give Plaintiff adequate warning of said dangerous and defective conditions and adequate warning would have altered Plaintiff's actions.

154. At all times relevant hereto, Defendant Bard Peripheral owed a duty to Plaintiff to properly manufacture, inspect, assemble, test and design the G2 Filter in order to make it safe for its intended use.

155. Defendant Bard Peripheral knew or should have reasonably discovered the defects and/or unreasonably dangerous conditions existing on, in and within the G2 Filter prior to placing said device into the stream of commerce.

156. Defendant Bard Peripheral knew or should have known that Plaintiff and users of the G2 Filter could foreseeably suffer injury as a result of Defendant's failure to exercise the ordinary and reasonable care described above. Defendant should have reasonably foreseen that Plaintiff and users of the G2 Filter would suffer serious injury or death as a result of filter fracture, fatigue, migration and/or perforation/piercing of vessels and organs associated with Filter failure and as such should have designed the product to prevent such injuries of the type sustained by Plaintiff.

157. As a direct and proximate result of Defendant Bard Peripheral's negligent acts and/or omissions, the G2 Filter was manufactured, sold and placed into the stream of commerce.

158. As a direct and proximate result of the defective manufacture, design and/or defective condition of the G2 Filter existing at the time of sale and/or when placed in the stream of

commerce making it unreasonably dangerous when put to a reasonably anticipated use; and the sale of the G2 Filter without the above-described and/or adequate warnings, the G2 Filter placed within the Plaintiff's body failed leading to fracture, fatigue, migration and/or perforation/piercing causing the filter to perforate, pierce and/or severely damage Plaintiff's vessels, body, organs and tissues and/or not otherwise operate properly leading to severe physical injury.

159. As a direct and proximate result of the defective manufacture, design and/or defective condition of the G2 Filter existing at the time of sale and/or when placed in the stream of commerce making it unreasonably dangerous when put to a reasonably anticipated use; and the sale of the G2 Filter without the above-described and/or adequate warnings, Plaintiff sustained serious physical injury as a result of Filter failure, including, but no limited to filter fracture, fatigue, migration and/or perforation/piercing of tissue, vessel and/or organs.

160. As a direct and proximate result of the defective manufacture, design and/or defective condition of the G2 Filter existing at the time of sale and/or when placed in the stream of commerce making it unreasonably dangerous when put to a reasonably anticipated use; and the sale of the G2 Filter without the above-described and/or adequate warnings, Plaintiff sustained serious physical injuries, including, but not limited to, bilateral above-knee amputations, injury to his scrotum and other internal injuries requiring hospitalization and on-going medical care and treatment.

161. As a direct and proximate result of the defective manufacture, design and/or defective condition of the G2 Filter existing at the time of sale and/or when placed in the stream of commerce making it unreasonably dangerous when put to a reasonably anticipated use; and the sale of the G2 Filter without the above-described and/or adequate warnings, Plaintiff

suffered and will in the future suffer emotional distress and/or other emotional, mental and/or psychological injuries requiring on-going psychological care and/or counseling.

162. As a direct and proximate result of the defective manufacture, design and/or defective condition of the G2 Filter existing at the time of sale and/or when placed in the stream of commerce making it unreasonably dangerous when put to a reasonably anticipated use; and the sale of the G2 Filter without the above-described and/or adequate warnings, Plaintiff has suffered, and will in the future suffer, great pain and suffering, both mental and physical and incurred, and will in the future incur, expenses for medical care and treatment, housing, transportation, equipment, and/or other facilities in an amount that is fair and reasonable.

163. As a direct and proximate result of the defective manufacture, design and/or defective condition of the G2 Filter existing at the time of sale and/or when placed in the stream of commerce making it unreasonably dangerous when put to a reasonably anticipated use; and the sale of the G2 Filter without the above-described and/or adequate warnings, Plaintiff has suffered, and will in the future suffer a loss of income, and other economic damages in an amount that is fair and reasonable.

164. Defendant Bard Peripheral's conduct was willful, wanton and malicious and showed a complete indifference to or conscious disregard for the safety of others, including Plaintiff, when it (1) continued to manufacture and place into the stream of commerce the G2 Filter with knowledge that said G2 Filter was defective and dangerous because of filter failure, including, filter fracture, fatigue, migration and perforation/piercing of vessels, organs and tissues; (2) took no steps to recall the G2 Filter from the market in a timely and safe manner; (3) failed to warn or inform Plaintiff, Physicians and the general public at large of those defects and dangers associated with the device and (4) made and continued to make false

representations regard the safety and improvement of the device.

WHEREFORE, Plaintiff George Leus prays for judgment on Count VI of his Complaint against Defendant Bard Peripheral Vascular, Inc., for actual damages in on amount that is fair and reasonable, for punitive and/or exemplary damages in an amount that will serve to punish Defendant and to deter Defendant and others from like conduct, for his costs and expenses incurred herein, and for any other such relief the Court deems just and proper in the premises.

COUNT VII
(Plaintiff v. Bard Peripheral Vascular, Inc.)
(Breach of Implied Warranty)

165. Plaintiff incorporates by reference each and every allegation set forth in paragraphs 1 through 54 herein.

166. Defendant Bard Peripheral was in the business of designing, developing, manufacturing, marketing and selling sophisticated medical devices, including the G2 Filter.

167. Defendant Bard Peripheral knew or should have known that the members of the general public, including Plaintiff, relied upon its skill and judgment to properly design, assemble, manufacture, test and inspect the G2 Filter.

168. At the time Defendant Bard Peripheral designed, manufactured, assembled, distributed and sold the G2 Filter it knew of the use for which it was intended and implied and warranted that the G2 Filter was of merchantable quality and safe for its intended use.

169. At the time Defendant Bard Peripheral designed, manufactured, produced, tested, studied, inspected, marketed, advertised, sold, promoted and/or distributed the G2 Filter for use by Plaintiff, it knew (1) of the potential for fracture, perforation of vessels, migration or other potential failures, and (2) they were manufactured in such a manner so that the exterior surface of the G2 Filter was inadequately prepared and/or finished thereby subjecting the

device to weakening and failure.

170. Plaintiff reasonably relied upon the skill and judgment of Defendant Bard Peripheral as to whether the G2 Filter was of merchantable quality and safe and fit for its intended use. Plaintiff had no knowledge that the G2 Filter was not safe and fit for its intended use.

171. Plaintiff and Defendant Bard Peripheral were in privity of contract.

172. The G2 Filter was used in a manner in which it was intended to be used.

173. Contrary to such implied warranty, Defendant Bard Peripheral's G2 Filter was not of merchantable quality, safe or fit for its intended use as described herein above because they were and are defective, failed to function as safely as an ordinary user would expect when used in an intended and reasonably foreseeable manner, and because they presented a substantial likelihood of failure, fracture, fatigue, migration and/or perforation of vessels.

174. Contrary to such implied warranty, the G2 Filter was not of merchantable quality or safe for its intended use because they were designed and manufacture in such a manner so that the exterior surface of the G2 Filter was inadequately, improperly and inappropriately prepared and/or finished, thereby subjecting the device to weakening and failure.

175. Defendant Bard Peripheral was a merchant with respect to the G2 Filter which was sold to Plaintiff and/or his representative and there was an implied warranty that the G2 Filter was merchantable.

176. Defendant Bard Peripheral breached the implied warranty in the contract for the sale of goods in that the G2 Filter was not fit for its intended purpose. Furthermore, the G2 Filter did not conform to the promises, representations or affirmations made by Defendant regarding the product.

177. As a direct and proximate result of Defendant Bard Peripheral's breach of implied warranty,

the G2 Filter placed within Plaintiff's body failed leading to fracture, fatigue, migration and/or perforation/piercing causing the filter to perforate, pierce and/or severely damage the Plaintiff's vessels, body, organs and tissues and/or not otherwise operate properly leading to severe physical injury.

178. As a direct and proximate result of Defendant Bard Peripheral's breach of implied warranty, Plaintiff sustained serious physical injury as a result of Filter failure, including, but not limited to filter fracture, fatigue, migration and/or perforation/piercing of tissue, vessel and/or organs.

179. As a direct and proximate result of Defendant Bard Peripheral's breach of implied warranty, Plaintiff sustained serious physical injuries, including, but not limited to, bilateral above- knee amputations, injury to his scrotum and other internal injuries requiring hospitalization and on-going medical care and treatment.

180. As a direct and proximate result of Defendant Bard Peripheral's breach of implied warranty, Plaintiff suffered and will in the future suffer emotional distress and/or other emotional, mental and/or psychological injuries requiring on-going psychological care and/or counseling.

181. As a direct and proximate result of Defendant Bard Peripheral's breach of implied warranty, Plaintiff has suffered, and will in the future suffer, great pain and suffering, both mental and physical and incurred, and will in the future incur, expenses for medical care and treatment, housing, transportation, equipment and/or other facilities in an amount that is fair and reasonable.

182. As a direct and proximate result of Defendant Bard Peripheral's breach of implied warranty, Plaintiff has suffered, and will in the future suffer a loss of income, and other economic damages in an amount that is fair and reasonable.

183. Defendant Bard Peripheral's conduct was willful, wanton and malicious and showed a

complete indifference to or conscious disregard for the safety of others including Plaintiff, when it (1) continued to manufacture and place into the stream of commerce the G2 Filter with knowledge that said G2 Filter was defective and dangerous because of filter failure, including, filter fracture, fatigue, migration and perforation/piercing of vessels, organs and tissues; (2) took no steps to recall the G2 Filter from the market in a timely and safe manner; (3) failed to warn or inform Plaintiff, Physicians and the general public at large of those defects and dangers associated with the device and (4) made and continued to make false representations regard the safety and improvement of the device.

WHEREFORE, Plaintiff George Leus prays for judgment on Count VII of his Complaint against Defendant Bard Peripheral Vascular, Inc., for actual damages in on amount that is fair and reasonable, for punitive and/or exemplary damages in an amount that will serve to punish Defendant and to deter Defendant and others from like conduct, for his costs and expenses incurred herein, and for any other such relief the Court deems just and proper in the premises.

COUNT VIII
(Plaintiff v. Bard Peripheral Vascular, Inc.)
(Fraudulent Concealment)

184. Plaintiff incorporates by reference each and every allegation set forth in paragraphs 1 through 54 herein.

185. At all times relevant hereto, Defendant Bard Peripheral was in the business of designing, developing, manufacturing, marketing and selling sophisticated medical devices, including the G2 Filter.

186. Defendant Bard Peripheral's G2 Filter was defectively manufactured and designed, such that it posed a substantial risk of failure, including fracture, fatigue, migration and perforation/piercing of vessels and organs and serious injury or death.

187. Defendant Bard Peripheral was aware of the defective nature of the G2 Filter and the risks and dangers associated therewith.

188. As the manufacturer, distributor, marketer and seller of sophisticated medical devices, including the G2 Filter, Defendant Bard Peripheral had a legal duty to fully disclose the hazards of its product to Plaintiff, the public at large and the medical community.

189. Defendant Bard Peripheral also owed a duty to disclose the hazardous nature of their G2 Filter to Plaintiff, the public at large and the medical community, because Defendant alone had knowledge of material facts, namely the hazardous nature of the G2 Filter which were not accessible to Plaintiffs, the public at the large and the medical community.

190. Defendant Bard Peripheral also owed a duty to disclose the hazardous nature of the G2 Filter to Plaintiff, the public at large and the medical community because Defendants made representations regarding the G2 Filter, but failed to disclose additional facts materially qualify the facts disclosed and/or which rendered the disclosures made likely to mislead Plaintiff, the public at large and the medical community.

191. Notwithstanding their knowledge of the hazardous nature of the G2 Filter, Defendant Bard Peripheral, at all material times hereto, concealed said hazards from Plaintiff, the public at large and the medical community, so that these groups or individuals would use or authorize use of the G2 Filter.

192. Plaintiff, the public at large and the medical community were unaware of the hazards of the G2 Filter and would not have acted as they did had they known of said hazards.

193. As a direct and proximate result of Defendant Bard Peripheral's fraudulent concealment of the hazards of the G2 Filter from Plaintiff, the public at large and the medical community, Defendant's G2 Filter was implanted in Plaintiff.

194. As a direct and proximate result of Defendant Bard Peripheral's fraudulent concealment of the hazards of the G2 Filter from Plaintiff, the public at large and the medical community, the G2 Filter placed within Plaintiff's body failed leading to fracture, fatigue, migration and/or perforation/piercing causing the filter to perforate, pierce and/or severely damage the Plaintiff's vessels, body, organs and tissues and/or not otherwise operate properly leading to severe physical injury.

195. Defendant Bard Peripheral's representation that its G2 Filter were safe for use, of sufficient strength and integrity and properly designed and manufactured were false and said representations were material in regards to the safety of the product and the use of said product by Plaintiff, the general public and the medical profession.

196. Defendant Bard Peripheral knew that said representations were false.

197. Defendant Bard Peripheral intended that the general public, the medical profession and Plaintiff rely and act upon on said representations and purchase, use and recommend the use of said product and that said actions in reliance upon said representations was reasonably contemplated.

198. Plaintiff, the general public and the medical profession were ignorant of the falsity of said representations and relied on said representations as being true.

199. Plaintiff, the general public and the medical profession had a right to and did rely upon said representations.

200. Plaintiff was injured as a direct and proximate result of said false representations made by defendant Bard Peripheral.

201. As a direct and proximate result of Defendant Bard Peripheral's false representations and fraudulent concealment of the hazards of the G2 Filter from Plaintiff, the public at large and

the medical community, Plaintiff sustained serious physical injury as a result of Filter failure, including, but not limited to filter fracture, fatigue, migration and/or perforation/piercing of tissue, vessel and/or organs.

202. As a direct and proximate result of Defendant Bard Peripheral's false representations and fraudulent concealment of the hazards of the G2 Filter from Plaintiff, the public at large and the medical community, Plaintiff sustained serious physical injuries, including, but not limited to, bilateral above-knee amputations, injury to his scrotum and other internal injuries requiring hospitalization and on-going medical care and treatment.

203. As a direct and proximate result of Defendant Bard Peripheral's false representations and fraudulent concealment of the hazards of the G2 Filter from Plaintiff, the public at large and the medical community, Plaintiff suffered and will in the future suffer emotional distress and/or other emotional, mental and/or psychological injuries requiring on-going psychological care and/or counseling.

204. As a direct and proximate result of Defendant Bard Peripheral's false representations and fraudulent concealment of the hazards of the G2 Filter from Plaintiff, the public at large and the medical community, Plaintiff has suffered, and will in the future suffer, great pain and suffering, both mental and physical and incurred, and will in the future incur, expenses for medical care and treatment, housing, transportation, equipment and/or other facilities in an amount that is fair and reasonable.

205. As a direct and proximate result of Defendant Bard Peripheral's false representations and fraudulent concealment of the hazards of the G2 Filter from Plaintiff, the public at large and the medical community, Plaintiff has suffered, and will in the future suffer a loss of income, and other economic damages in an amount that is fair and reasonable.

206. Defendant Bard Peripheral's conduct was willful, wanton and malicious and showed a complete indifference to or conscious disregard for the safety of others, including Plaintiff, when it (1) continued to manufacture and place into the stream of commerce the G2 Filter with knowledge that said G2 Filter was defective and dangerous because of filter failure, including, filter fracture, fatigue, migration and perforation/piercing of vessels, organs and tissues; (2) took no steps to recall the G2 Filter from the market in a timely and safe manner; (3) failed to warn or inform Plaintiff, Physicians and the general public at large of those defects and dangers associated with the device and (4) made and continued to make false representations regard the safety and improvement of the device.

WHEREFORE, Plaintiff George Leus prays for judgment on Count VIII of his Complaint against Defendant Bard Peripheral Vascular, Inc., for actual damages in on amount that is fair and reasonable, for punitive and/or exemplary damages in an amount that will serve to punish Defendant and to deter Defendant and others from like conduct, for his costs and expenses incurred herein, and for any other such relief the Court deems just and proper in the premises.

COUNT IX
(Plaintiff v. Doe Defendants)
(Negligence)

207. Plaintiff incorporates by reference each and every allegation set forth in paragraphs 1 through 54 herein.

208. Doe Defendants had a duty to exercise reasonable care in the design, manufacture, assembly, sale, distribution, installation, testing and inspection of the G2 Filter at the time it placed it in the stream of commerce, including a duty to assure that the product did not cause users to suffer unnecessary injury.

209. Doe Defendants failed to exercise reasonable care in the design, manufacture, assembly, sale, distribution, installation, testing and inspection of the G2 Filter by placing it into the stream of commerce in that Defendant knew or should have known that the device was dangerous and defective due to filter failure, including fracture, migration and/or perforation/piercing of tissues, vessels and organs, and insufficient strength and structural integrity.

210. Doe Defendants were negligent and failed to exercise reasonable care in the design, manufacture, assembly, sale, distribution, installation, inspection and testing of the G2 Filter as follows:

(a) in failing to properly prepare the exterior surface of the G2 Filter prior to completion of the manufacturing process;

(b) in failing to properly prepare the exterior surface of the G2 Filter during the manufacturing process so as to eliminate “drawing marking”;

(c) in manufacturing the G2 Filter with “drawing markings”;

(d) in failing to design the G2 Filter to be able to withstand the normal anatomical and physiological loading cycles exerted in vivo;

(e) in failing to manufacture the G2 Filter to be able withstand the normal anatomical physiological loading cycles exerted in vivo;

(f) in failing to design the G2 Filter to prevent fracture of the device following insertion;

(g) in failing to properly manufacture the G2 Filter to prevent fracture of the device following insertion;

(h) in failing to design the G2 Filter to prevent perforation and/or piercing of the vascular lumen and/or other tissue, organs and vessels;

(i) in failing to properly manufacture the G2 Filter to prevent perforation and/or piercing of the vascular lumen and/or other tissue, organs and vessels;

(j) in failing to properly prepare the exterior surface of the G2 Filter during the manufacturing process so as to eliminate "circumferential grinding markings";

(k) in manufacturing the G2 Filter with "circumferential grinding markings";

(l) in failing to properly manufacture the G2 Filter to prevent failure following insertion;

(m) in failing to properly design the G2 Filter to prevent failure following insertion;

(n) in manufacturing the G2 Filter with cracks, flaws and gouges in the alloy which makes up the device;

(o) in manufacturing the G2 Filter with exterior defects such as cracks, flaws, gouges, "drawing markings" and "circumferential grinding markings" making the device more significantly susceptible to fatigue failure, fracture, piercing and perforation;

(p) in failing to electro-polish the exterior surfaces of the G2 Filter prior to the completion of the manufacturing process;

(q) in failing to properly electro-polish the G2 Filter prior to the completion of the manufacturing process;

(r) in failing to design the G2 Filter to include electro-polishing, including, but not limited to the exterior surfaces of the device;

(s) in failing to electro-polish the Nitinol material of the G2 Filter as part of the manufacturing process;

(t) in failing to design the G2 Filter to include electro-polishing of the Nitinol material of the device;

(u) in failing to take those steps necessary during the manufacturing process to eliminate

surface blemishes, drawing markings and circumferential grinding markings of the exterior surface of the device, including, but not limited to the Nitinol material utilized on the G2 Filter;

(v) in failing to design the G2 Filter in such a manner as to prevent an unreasonable risk of filter failure, including, but not limited to fracture, fatigue, migration and/or perforation/piercing of the lumen, vessels, tissues and organs;

(w) in failing to manufacture the G2 Filter in such a manner as to prevent an unreasonable risk of filter failure, including, but not limited fracture, fatigue, migration and/or perforation/piercing of the lumen, vessels, tissues and organs;

(x) in failing to design the G2 Filter so as to prevent an unreasonable risk of filter fracture, fatigue, perforation of vessels and/or organs, migration of the device and/or portions of the device;

(y) in failing to manufacture the G2 Filter so as to prevent an unreasonable risk of filter fracture, fatigue, perforation of vessels and/or organs, migration of the device and/or portions of the device;

(z) in designing the G2 Filter so as to have unreasonable and insufficient strength and/or structural integrity to withstand normal placement within the human body;

(aa) in manufacturing the G2 Filter so as to have unreasonable and insufficient strength and/or structural integrity to withstand normal placement within the human body;

(bb) in designing the G2 Filter so as to be insufficient to withstand the foreseeable use of placement in the human body;

(cc) in manufacturing the G2 Filter such that the exterior surface was inadequately, improperly and inappropriately prepared and/or finished, causing the device to weaken

and fail leading to filter fracture, perforation of vessels and/or organs and migration of the device and/or portions of the device;

(dd) in designing the G2 Filter such that that exterior surface was inadequately, improperly and inappropriately prepared and/or finished causing the device to weaken and fail, leading to filter fracture, perforation or vessels and/or organs and migration of the device and/or portions of the device.

(ee) in failing to recall the G2 Filter in a timely and safe fashion;

(ff) in failing to notify and/or inform the Consumer Product Safety Commission that the G2 Filter that injured Plaintiff and which is the subject matter of this litigation contained a defect in the form of filter failure which could create a substantial product hazard or created an unreasonable risk of serious injury or death;

(gg) in failing to properly notify and/or warn of the dangers and risks of harm associated with the G2 Filter, namely, the incidence of filter failure, filter fracture, fatigue, perforation of vessels and/or organs and migration of the device and/or portions of the device;

(hh) in failing to properly warn Plaintiff, Physicians and the general public of the dangers and risks of harm associated with the G2 Filter, including, but not limited to filter failure, filter fracture, fatigue and perforation/piercing of vessels and organs;

(ii) in failing to properly warn Plaintiff, Physicians and the general public of the high incidence of filter failure, filter fracture, fatigue and perforation/ piercing of vessels and organs following insertions of the G2 Filter;

(jj) in failing to warn Plaintiff, Physicians and the general public that insertion of the G2 Filter placed patients at a “substantial” risk and/or danger of harm from filter failure,

filter fracture, fatigue and perforation/piercing of vessels and organs;

(kk) in failing to properly warn of the dangers and risks of harm associated with the G2 Filter, namely, the high incidence of filter failure;

(ll) in failing to provide adequate warnings to apprise/notify Plaintiff, members of the medical community and the general public of the substantial hazards posed by the G2 Filters, including the significant and actual risk that the G2 Filters would fail and/or fracture resulting in injury, including, but not limited to the hemorrhage, damage, destruction and/or the perforation of tissues, vessels and organs;

(mm) in failing to provide adequate warnings to apprise/notify Plaintiff, members of the medical community and the general public of the actual incidence of failure of the Recovery Filter System and G2 Filter;

(nn) in failing to provide adequate warnings to apprise/notify Plaintiff, members of the medical community and the general public that the G2 Filter was not electro-polished; as was standard in the industry;

(oo) in failing to use ordinary care to manufacture the G2 Filter to be reasonably safe when put to its intended use;

(pp) in failing to use ordinary care to design the G2 Filter to be reasonably safe when put to its intended use;

(qq) in placing the G2 Filter into the stream of commerce when it knew or should have known of its dangerous condition;

(rr) in failing to warn and/or properly notify Plaintiff and users of the G2 Filter of the unreasonably dangerous conditions existing on an within the G2 Filter including, but not limited to, filter failure and fatigue leading to migration, fracture and/or

perforation/piercing of vessels, organs and tissues;

(ss) in failing to properly assemble the G2 Filter;

(tt) in failing to inform the Consumer Product Safety Commission that filter failures, fatigue fracture, migration and/or perforation of vessels associated with the G2 Filter created a substantial product hazard (or) created an unreasonable risk of serious injury or death;

(uu) in failing to adhere and/or follow the provisions of the Consumer Product Safety Act;

(vv) in failing to properly manufacture the G2 Filter;

(ww) in failing to properly design the G2 Filter; and

(xx) in manufacturing the G2 Filter so as to be insufficient to withstand the forseeable use of placement in the human body.

211. Doe Defendants knew or should have reasonably discovered the defects and/or unreasonably dangerous conditions existing on, in and within the G2 Filter prior to placing said device into the stream of commerce.

212. Doe Defendants knew or should have known that Plaintiff and users of the G2 Filter could foreseeably suffer injury as a result of Defendant's failure to exercise the ordinary and reasonable care described above. Defendant should have reasonably foreseen that Plaintiff and users of the G2 Filter would suffer serious injury or death as a result of filter fracture, fatigue migration and/or perforation/piercing of vessels and organs associated with Filter failure and as such should have designed the product to prevent such injuries of the type sustained by Plaintiff.

213. At all times relevant hereto, Doe Defendants owed a duty to Plaintiff to properly

manufacture, inspect, assemble, test and design the G2 Filter in order to make it safe for its intended use.

214. As a direct and proximate result of Doe Defendant's negligent acts and/or omissions, the G2 Filter was manufactured, sold and placed into the stream of commerce.

215 As a direct and proximate result of Doe Defendant's negligent acts and/or omissions and the defective and unreasonably dangerous conditions of, on and within the G2 Filter, the G2 Filter placed within Plaintiff's body failed leading to fracture, fatigue, migration and/or perforation/piercing causing the filter to perforate, pierce and/or severely damage the Plaintiff's vessels, body, organs and tissues and/or not otherwise operate properly leading to severe physical injury.

216 As a direct and proximate result of Doe Defendant's negligent acts and/or omissions and the defective and unreasonably dangerous conditions of, on and within the G2 Filter, Plaintiff sustained serious physical injury as a result of Filter failure, including, but not limited to filter fracture, fatigue, migration and/or perforation/piercing of tissue, vessel and/or organs.

217 As a direct and proximate result of Doe Defendant's negligent acts and/or omissions and the defective and unreasonably dangerous conditions of, on and within the G2 Filter, Plaintiff sustained serious physical injuries, including, but not limited to, bilateral above-knee amputations, injury to his scrotum and other internal injuries requiring hospitalization and on-going medical care and treatment.

218. As a direct and proximate result of Doe Defendant's negligent acts and/or omissions and the defective and unreasonably dangerous conditions of, on and within the G2 Filter, Plaintiff suffered and will in the future suffer emotional distress and/or other emotional, mental and/or psychological injuries requiring on-going psychological care and/or counseling.

219. As a direct and proximate result of Doe Defendant's negligent acts and/or omissions and the defective and unreasonably dangerous conditions of, on and within the G2 Filter, Plaintiff has suffered, and will in the future suffer, great pain and suffering, both mental and physical and incurred, and will in the future incur, expenses for medical care and treatment, housing, transportation, equipment and/or other facilities in an amount that is fair and reasonable.

220. As a direct and proximate result of Doe Defendant's negligent acts and/or omissions and the defective and unreasonably dangerous conditions of, on and within the G2 Filter, Plaintiff has suffered, and will in the future suffer a loss of income, and other economic damages in an amount that is fair and reasonable.

221. Doe Defendant's conduct was willful, wanton and malicious and showed a complete indifference to or conscious disregard for the safety of others, including Plaintiff, when it (1) continued to manufacture and place into the stream of commerce the G2 Filter with knowledge that said G2 Filter was defective and dangerous because of filter failure, including, filter fracture, fatigue, migration and perforation/piercing of vessels, organs and tissues; (2) took no steps to recall the G2 Filter from the market in a timely and safe manner; (3) failed to warn or inform Plaintiff, Physicians and the general public at large of those defects and dangers associated with the device and (4) made and continued to make false representations regard the safety and improvement of the device.

WHEREFORE, Plaintiff George Leus prays for judgment on Count IX of his Complaint against Doe Defendants for actual damages in an amount that is fair and reasonable, for punitive and/or exemplary damages in an amount that will serve to punish Doe Defendants and to deter Defendant and others from like conduct, for his costs and expenses incurred herein, and for any other such relief the Court deems just and proper in the premises.

COUNT X
(Plaintiff v. Doe Defendants)
(Strict Liability)

222. Plaintiff incorporates by reference each and every allegation set forth in paragraphs 1 through 54 herein.

223. Doe Defendants transferred and/or sold the G2 Filter in the normal course of business.

224. Plaintiff utilized the G2 Filter in the manner reasonably anticipated and Defendant should have reasonably foreseen that patients such as Plaintiff would suffer serious injury or death as a result of filter failure causing fracture, fatigue, migration and/or perforation/piercing of vessels, tissue and organs and Defendant should have designed the product (G2 Filter) so that injuries do not occur, including, but not limited to the type sustained by Plaintiff.

225. Doe Defendants placed into the stream of commerce the G2 Filter which is an unreasonably dangerous product.

226. The G2 Filter was then in a defective condition unreasonably dangerous when put to a reasonably anticipated use without knowledge of its characteristics when Doe Defendants sold the G2 Filter and/or placed it in the stream of commerce in that Doe Defendants :

(a) failed to properly prepare the exterior surface of the G2 Filter prior to completion of the manufacturing process;

(b) failed to properly prepare the exterior surface of the G2 Filter during the manufacturing process so as to eliminate “drawing marking”;

(c) manufactured the G2 Filter with “drawing markings”;

(d) failed to design the G2 Filter to be able to withstand the normal anatomical and physiological loading cycles exerted in vivo;

(e) failed to manufacture the G2 Filter to be able withstand the normal anatomical and

physiological loading cycles exerted in vivo;

(f) failed to design the G2 Filter to prevent fracture of the device following insertion;

(g) failed to properly manufacture the G2 Filter to prevent fracture of the device following insertion;

(h) failed to design the G2 Filter to prevent perforation and/or piercing of the vascular lumen and/or other tissue, organs and vessels;

(i) failed to properly manufacture the G2 Filter to prevent perforation and/or piercing of the vascular lumen and/or other tissue, organs and vessels;

(j) failed to properly prepare the exterior surface of the G2 Filter during the manufacturing process so as to eliminate "circumferential grinding markings";

(k) manufactured the G2 Filter with "circumferential grinding markings";

(l) failed to properly manufacture the G2 Filter to prevent failure following insertion;

(m) failed to properly design the G2 Filter to prevent failure following insertion;

(n) manufactured the G2 Filter with cracks, flaws and gouges in the alloy which makes up the device;

(o) manufactured the G2 Filter with exterior defects such as cracks, flaws, gouges, "drawing markings" and "circumferential grinding markings" making the device more significantly susceptible to fatigue failure, fracture, piercing and perforation;

(p) failed to electro-polish the exterior surfaces of the G2 Filter prior to the completion of the manufacturing process;

(q) failed to properly electro-polish the G2 Filter prior to the completion of the manufacturing process;

(r) failed to design the G2 Filter to include electro-polishing, including, but not limited to the

exterior surfaces of the device;

(s) failed to electro-polish the Nitinol material of the G2 Filter as part of the manufacturing process;

(t) failed to design the G2 Filter to include electro-polishing of the Nitinol material of the device;

(u) failed to take those steps necessary during the manufacturing process to eliminate surface blemishes, drawing markings and circumferential grinding markings of the exterior surface of the device, including, not limited to the Nitinol material utilized on the G2 Filter;

(v) failed to design the G2 Filter in such a manner as to prevent an unreasonable risk of filter failure, including, but not limited to fracture, fatigue, migration and/or perforation/piercing of the lumen, vessels, tissues and organs;

(w) failed to manufacture the G2 Filter in such a manner as to prevent an unreasonable risk of filter failure, including, but not limited fracture, fatigue, migration and/or perforation/piercing of the lumen, vessels, tissues and organs;

(x) failed to design the G2 Filter so as to prevent an unreasonable risk of filter fracture, fatigue, perforation of vessels and/or organs, migration of the device and/or portions of the device;

(y) failed to manufacture the G2 Filter so as to prevent an unreasonable risk of filter fracture, fatigue, perforation of vessels and/or organs, migration of the device and/or portions of the device;

(z) designed the G2 Filter so as to have unreasonable and insufficient strength and/or structural integrity to withstand normal placement within the human body;

(aa) manufactured the G2 Filter so as to have unreasonable and insufficient strength and/or structural integrity to withstand normal placement within the human body;

(bb) designed the G2 Filter so as to be insufficient to withstand the foreseeable use of placement in the human body;

(cc) manufactured the G2 Filter such that the exterior surface was inadequately, improperly and inappropriately prepared and/or finished, causing the device to weaken and fail leading to filter fracture, perforation of vessels and/or organs and migration of the device and/or portions of the device;

(dd) designed the G2 Filter such that that exterior surface was inadequately improperly and inappropriately prepared and/or finished causing the device to weaken and fail, leading to filter fracture, perforation or vessels and/or organs and migration of the device and/or portions of the device.

(ee) failed to recall the G2 Filter in a timely and safe fashion;

(ff) failed to notify and/or inform the Consumer Product Safety Commission that the G2 Filter that injured Plaintiff and which is the subject matter of this litigation contained a defect in the form of filter failure which could create a substantial product hazard or created an unreasonable risk of serious injury or death;

(gg) failed to properly notify and/or warn of the dangers and risks of harm associated with the G2 Filter, namely, the incidence of filter failure, filter fracture, fatigue, perforation of vessels and/or organs and migration of the device and/or portions of the device;

(hh) failed to properly warn Plaintiff, Physicians and the general public of the dangers and risks of harm associated with the G2 Filter, including, but not limited to filter failure, filter fracture, fatigue and perforation/piercing of vessels and organs;

(ii) failed to properly warn Plaintiff, Physicians and the general public of the high incidence of filter failure, filter fracture, fatigue and perforation/ piercing of vessels and organs following insertions of the G2 Filter;

(jj) failed to warn Plaintiff, Physicians and the general public that insertion of the G2 Filter placed patients at a "substantial" risk and/or danger of harm from filter failure, filter fracture, fatigue and perforation/piercing of vessels and organs;

(kk) failed to properly warn of the dangers and risks of harm associated with the G2 Filter, namely, the high incidence of filter failure;

(ll) failed to provide adequate warnings to apprise/notify Plaintiff, members of the medical community and the general public of the substantial hazards posed by the G2 Filters, including the significant and actual risk that the G2 Filters would fail and/or fracture resulting in injury, including but not limited, to the hemorrhage, damage, destruction and the perforation of tissues, vessels and organs;

(mm) failed to provide adequate warnings to apprise/notify Plaintiff, members of the medical community and the general public of the actual incidence of failure of the Recovery Filter System and G2 Filter;

(nn) failed to provide adequate warnings to apprise/notify Plaintiff, members of the medical community and the general public that the G2 Filter was not electro-polished; as was standard in the industry;

(oo) failed to use ordinary care to manufacture the G2 Filter to be reasonably safe when put to its intended use;

(pp) failed to use ordinary care to design the G2 Filter to be reasonably safe when put to its intended use;

(qq) placed the G2 Filter into the stream of commerce when it knew or should have known of its dangerous condition;

(rr) failed to warn and/or properly notify Plaintiff and users of the G2 Filter of the unreasonably dangerous conditions existing on an within the G2 Filter including, but not limited to, filter failure and fatigue leading to migration, fracture and/or perforation/piercing of vessels, organs and tissues;

(ss) failed to properly assemble the G2 Filter;

(tt) failed to inform the Consumer Product Safety Commission that filter failures, fracture, fatigue, migration and/or perforation of vessels associated with the G2 Filter, created a substantial product hazard (or) created an unreasonable risk of serious injury or death;

(uu) failed to adhere and/or follow the provisions of the Consumer Product Safety Act;

(vv) failed to properly manufacture the G2 Filter;

(ww) failed to properly design the G2 Filter; and

(xx) manufactured the G2 Filter so as to be insufficient to withstand the foreseeable use of placement in the human body.

227. The G2 Filter was in a defective condition and unreasonably dangerous when put to a reasonably anticipated use and such defective condition existed when the product was sold and placed in the stream of commerce.

228. Plaintiff had no knowledge of the defective conditions existing in, on and within the G2 Filter and that said G2 Filter was dangerous.

229. Doe Defendants did not give Plaintiff adequate warning of said dangerous and defective conditions and adequate warning would have altered Plaintiff's actions.

230. At all times relevant hereto, Doe Defendants owed a duty to Plaintiff to properly

manufacture, inspect, assemble, test and design the G2 Filter in order to make it safe for its intended use.

231. Doe Defendants knew or should have reasonably discovered the defects and/or unreasonably dangerous conditions existing on, in and within the G2 Filter prior to placing said device into the stream of commerce.

232. Doe Defendants knew or should have known that Plaintiff and users of the G2 Filter could foreseeably suffer injury as a result of Defendant's failure to exercise the ordinary and reasonable care described above. Defendant should have reasonably foreseen that Plaintiff and users of the G2 Filter would suffer serious injury or death as a result of filter fracture, fatigue, migration and/or perforation/piercing of vessels and organs associated with Filter failure and as such should have designed the product to prevent such injuries of the type sustained by Plaintiff.

233. As a direct and proximate result of Doe Defendant's negligent acts and/or omissions, the G2 Filter was manufactured, sold and placed into the stream of commerce.

234. As a direct and proximate result of the defective manufacture, design and/or defective condition of the G2 Filter existing at the time of sale and/or when placed in the stream of commerce making it unreasonably dangerous when put to a reasonably anticipated use; and the sale of the G2 Filter without the above-described and/or adequate warnings, the G2 Filter placed within the Plaintiff's body failed leading to fracture, fatigue, migration and/or perforation/piercing causing the filter to perforate, pierce and/or severely damage Plaintiff's vessels, body, organs and tissues and/or not otherwise operate properly leading to severe physical injury.

235. As a direct and proximate result of the defective manufacture, design and/or defective

condition of the G2 Filter existing at the time of sale and/or when placed in the stream of commerce making it unreasonably dangerous when put to a reasonably anticipated use; and the sale of the G2 Filter without the above-described and/or adequate warnings, Plaintiff sustained serious physical injury as a result of Filter failure, including, but no limited to filter fracture, fatigue, migration and/or perforation/piercing of tissue, vessel and/or organs.

236. As a direct and proximate result of the defective manufacture, design and/or defective condition of the G2 Filter existing at the time of sale and/or when placed in the stream of commerce making it unreasonably dangerous when put to a reasonably anticipated use; and the sale of the G2 Filter without the above-described and/or adequate warnings, Plaintiff sustained serious physical injuries, including, but not limited to, bilateral above-knee amputations, injury to his scrotum and other internal injuries requiring hospitalization and on-going medical care and treatment.

237. As a direct and proximate result of the defective manufacture, design and/or defective condition of the G2 Filter existing at the time of sale and/or when placed in the stream of commerce making it unreasonably dangerous when put to a reasonably anticipated use; and the sale of the G2 Filter without the above-described and/or adequate warnings, Plaintiff suffered and will in the future suffer emotional distress and/or other emotional, mental and/or psychological injuries requiring on-going psychological care and/or counseling.

238. As a direct and proximate result of the defective manufacture, design and/or defective condition of the G2 Filter existing at the time of sale and/or when placed in the stream of commerce making it unreasonably dangerous when put to a reasonably anticipated use; and the sale of the G2 Filter without the above-described and/or adequate warnings, Plaintiff has suffered, and will in the future suffer, great pain and suffering, both mental and physical and

incurred, and will in the future incur, expenses for medical care and treatment, housing, transportation, equipment, and/or other facilities in an amount that is fair and reasonable.

239. As a direct and proximate result of the defective manufacture, design and/or defective condition of the G2 Filter existing at the time of sale and/or when placed in the stream of commerce making it unreasonably dangerous when put to a reasonably anticipated use; and the sale of the G2 Filter without the above-described and/or adequate warnings, Plaintiff has suffered, and will in the future suffer a loss of income, and other economic damages in an amount that is fair and reasonable.

240. Doe Defendant's conduct was willful, wanton and malicious and showed a complete indifference to or conscious disregard for the safety of others, including Plaintiff, when it (1) continued to manufacture and place into the stream of commerce the G2 Filter with knowledge that said G2 Filter was defective and dangerous because of filter failure, including, filter fracture, fatigue, migration and perforation/piercing of vessels, organs and tissues; (2) took no steps to recall the G2 Filter from the market in a timely and safe manner; (3) failed to warn or inform Plaintiff, Physicians and the general public at large of those defects and dangers associated with the device and (4) made and continued to make false representations regard the safety and improvement of the device.

WHEREFORE, Plaintiff George Leus prays for judgment on Count X of his Complaint against Doe Defendants for actual damages in on amount that is fair and reasonable, for punitive and/or exemplary damages in an amount that will serve to punish Doe Defendants and to deter Defendant and others from like conduct, for his costs and expenses incurred herein, and for any other such relief the Court deems just and proper in the premises.

COUNT XI
(Plaintiff v. Doe Defendants)
(Breach of Implied Warranty)

241. Plaintiff incorporates by reference each and every allegation set forth in paragraphs 1 through 54 herein.

242. Doe Defendants were in the business of designing, developing, manufacturing, marketing and selling sophisticated medical devices, including the G2 Filter.

243. Doe Defendants knew or should have known that the members of the general public, including Plaintiff, relied upon its skill and judgment to properly design, assemble, manufacture, test and inspect the G2 Filter.

244. At the time Doe Defendants designed, manufactured, assembled, distributed and sold the G2 Filter it knew of the use for which it was intended and implied and warranted that the G2 Filter was of merchantable quality and safe for its intended use.

245. At the time Doe Defendants designed, manufactured, produced, tested, studied, inspected, marketed, advertised, sold, promoted and/or distributed the G2 Filter for use by Plaintiff, it knew (1) of the potential for fracture, perforation of vessels, migration or other potential failures, and (2) they were manufactured in such a manner so that the exterior surface of the G2 Filter was inadequately prepared and/or finished thereby subjecting the device to weakening and failure.

246. Plaintiff reasonably relied upon the skill and judgment of Doe Defendants as to whether the G2 Filter was of merchantable quality and safe and fit for its intended use. Plaintiff had no knowledge that the G2 Filter was not safe and fit for its intended use.

247. Plaintiff and Doe Defendants were in privity of contract.

248. The G2 Filter was used in a manner in which it was intended to be used.

249. Contrary to such implied warranty, Doe Defendant's G2 Filter was not of merchantable quality, safe or fit for its intended use as described herein above because they were and are defective, failed to function as safely as an ordinary user would expect when used in an intended and reasonably foreseeable manner, and because they presented a substantial likelihood of failure, fracture, fatigue, migration and/or perforation of vessels.

250. Contrary to such implied warranty, the G2 Filter was not of merchantable quality or safe for its intended use because they were designed and manufacture in such a manner so that the exterior surface of the G2 Filter was inadequately, improperly and inappropriately prepared and/or finished, thereby subjecting the device to weakening and failure.

251. Doe Defendants were merchants with respect to the G2 Filter which was sold to Plaintiff and/or his representative and there was an implied warranty that the G2 Filter was merchantable.

252. Doe Defendants breached the implied warranty in the contract for the sale of goods in that the G2 Filter was not fit for its intended purpose. Furthermore, the G2 Filter did not conform to the promises, representations or affirmations made by Defendant regarding the product.

253. As a direct and proximate result of Doe Defendant's breach of implied warranty, the G2 Filter placed within Plaintiff's body failed leading to fracture, fatigue, migration and/or perforation/piercing causing the filter to perforate, pierce and/or severely damage the Plaintiff's vessels, body, organs and tissues and/or not otherwise operate properly leading to severe physical injury.

254. As a direct and proximate result of Doe Defendant's breach of implied warranty, Plaintiff sustained serious physical injury as a result of Filter failure, including, but not

limited to filter fracture, fatigue, migration and/or perforation/piercing of tissue, vessel and/or organs.

255. As a direct and proximate result of Doe Defendant's breach of implied warranty, Plaintiff sustained serious physical injuries, including, but not limited to, bilateral above-knee amputations, injury to his scrotum and other internal injuries requiring hospitalization and on-going medical care and treatment.

256. As a direct and proximate result of Doe Defendant's breach of implied warranty, Plaintiff suffered and will in the future suffer emotional distress and/or other emotional, mental and/or psychological injuries requiring on-going psychological care and/or counseling.

257. As a direct and proximate result of Doe Defendant's breach of implied warranty, Plaintiff has suffered, and will in the future suffer, great pain and suffering, both mental and physical and incurred, and will in the future incur, expenses for medical care and treatment, housing, transportation, equipment and/or other facilities in an amount that is fair and reasonable.

258. As a direct and proximate result of Doe Defendant's breach of implied warranty, Plaintiff has suffered, and will in the future suffer a loss of income, and other economic damages in an amount that is fair and reasonable.

259. Doe Defendant's conduct was willful, wanton and malicious and showed a complete indifference to or conscious disregard for the safety of others including Plaintiff, when it (1) continued to manufacture and place into the stream of commerce the G2 Filter with knowledge that said G2 Filter was defective and dangerous because of filter failure, including, filter fracture, fatigue, migration and perforation/piercing of vessels, organs and

tissues; (2) took no steps to recall the G2 Filter from the market in a timely and safe manner; (3) failed to warn or inform Plaintiff, Physicians and the general public at large of those defects and dangers associated with the device and (4) made and continued to make false representations regard the safety and improvement of the device.

WHEREFORE, Plaintiff George Leus prays for judgment on Count XI of his Complaint against Doe Defendants for actual damages in on amount that is fair and reasonable, for punitive and/or exemplary damages in an amount that will serve to punish Doe Defendant and to deter Defendant and others from like conduct, for his costs and expenses incurred herein, and for any other such relief the Court deems just and proper in the premises.

COUNT XII
(Plaintiff v. Doe Defendants)
(Fraudulent Concealment)

260. Plaintiff incorporates by reference each and every allegation set forth in paragraphs 1 through 54 herein.

261. At all times relevant hereto, Doe Defendants were in the business of designing, developing, manufacturing, marketing and selling sophisticated medical devices, including the G2 Filter.

262. Doe Defendants G2 Filter was defectively manufactured and designed, such that it posed a substantial risk of failure, including fracture, fatigue, migration and perforation/piercing of vessels and organs and serious injury or death.

263. Doe Defendants were aware of the defective nature of the G2 Filter and the risks and dangers associated therewith.

264. As the manufacturer, distributor, marketer and seller of sophisticated medical devices, including the G2 Filter, Doe Defendants had a legal duty to fully disclose the hazards

of its product to Plaintiff, the public at large and the medical community.

265. Doe Defendants also owed a duty to disclose the hazardous nature of their G2 Filter to Plaintiff, the public at large and the medical community, because Defendant alone had knowledge of material facts, namely the hazardous nature of the G2 Filter which were not accessible to Plaintiffs, the public at the large and the medical community.

266. Doe Defendants also owed a duty to disclose the hazardous nature of the G2 Filter to Plaintiff, the public at large and the medical community because Defendants made representations regarding the G2 Filter, but failed to disclose additional facts materially qualify the facts disclosed and/or which rendered the disclosures made likely to mislead Plaintiff, the public at large and the medical community.

267. Notwithstanding their knowledge of the hazardous nature of the G2 Filter, Doe Defendants, at all material times hereto, concealed said hazards from Plaintiff, the public at large and the medical community, so that these groups or individuals would use or authorize use of the G2 Filter.

268. Plaintiff, the public at large and the medical community were unaware of the hazards of the G2 Filter and would not have acted as they did had they known of said hazards.

269. As a direct and proximate result of Doe Defendant's fraudulent concealment of the hazards of the G2 Filter from Plaintiff, the public at large and the medical community, Defendant's G2 Filter was implanted in Plaintiff.

270. As a direct and proximate result of Doe Defendant's fraudulent concealment of the hazards of the G2 Filter from Plaintiff, the public at large and the medical community, the G2 Filter placed within Plaintiff's body failed leading to fracture, fatigue, migration and/or perforation/piercing causing the filter to perforate, pierce and/or severely damage the

Plaintiff's vessels, body, organs and tissues and/or not otherwise operate properly leading to severe physical injury.

271. Doe Defendant's representation that its G2 Filter were safe for use, of sufficient strength and integrity and properly designed and manufactured were false and said representations were material in regards to the safety of the product and the use of said product by Plaintiff, the general public and the medical profession.

272. Doe Defendants knew that said representations were false.

273. Doe Defendants intended that the general public, the medical profession and Plaintiff rely and act upon on said representations and purchase, use and recommend the use of said product and that said actions in reliance upon said representations was reasonably contemplated.

274. Plaintiff, the general public and the medical profession were ignorant of the falsity of said representations and relied on said representations as being true.

275. Plaintiff, the general public and the medical profession had a right to and did rely upon said representations.

276. Plaintiff was injured as a direct and proximate result of said false representations made by Doe Defendants.

277. As a direct and proximate result of Doe Defendant's false representations and fraudulent concealment of the hazards of the G2 Filter from Plaintiff, the public at large and the medical community, Plaintiff sustained serious physical injury as a result of Filter failure, including, but not limited to filter fracture, fatigue, migration and/or perforation/piercing of tissue, vessel and/or organs.

278. As a direct and proximate result of Doe Defendant's false representations and fraudulent

concealment of the hazards of the G2 Filter from Plaintiff, the public at large and the medical community, Plaintiff sustained serious physical injuries, including, but not limited to, bilateral above-knee amputations, injury to his scrotum and other internal injuries requiring hospitalization and on-going medical care and treatment.

279. As a direct and proximate result of Doe Defendant's false representations and fraudulent concealment of the hazards of the G2 Filter from Plaintiff, the public at large and the medical community, Plaintiff suffered and will in the future suffer emotional distress and/or other emotional, mental and/or psychological injuries requiring on-going psychological care and/or counseling.

280. As a direct and proximate result of Doe Defendant's false representations and fraudulent concealment of the hazards of the G2 Filter from Plaintiff, the public at large and the medical community, Plaintiff has suffered, and will in the future suffer, great pain and suffering, both mental and physical and incurred, and will in the future incur, expenses for medical care and treatment, housing, transportation, equipment and/or other facilities in an amount that is fair and reasonable.

281. As a direct and proximate result of Doe Defendant's false representations and fraudulent concealment of the hazards of the G2 Filter from Plaintiff, the public at large and the medical community, Plaintiff has suffered, and will in the future suffer a loss of income, and other economic damages in an amount that is fair and reasonable.

282. Doe Defendant's conduct was willful, wanton and malicious and showed a complete indifference to or conscious disregard for the safety of others, including Plaintiff, when it (1) continued to manufacture and place into the stream of commerce the G2 Filter with knowledge that said G2 Filter was defective and dangerous because of filter failure,

including, filter fracture, fatigue, migration and perforation/piercing of vessels, organs and tissues; (2) took no steps to recall the G2 Filter from the market in a timely and safe manner; (3) failed to warn or inform Plaintiff, Physicians and the general public at large of those defects and dangers associated with the device and (4) made and continued to make false representations regard the safety and improvement of the device.

WHEREFORE, Plaintiff George Leus prays for judgment on Count XII of his Complaint against Doe Defendants for actual damages in on amount that is fair and reasonable, for punitive and/or exemplary damages in an amount that will serve to punish Doe Defendant and to deter Defendant and others from like conduct, for his costs and expenses incurred herein, and for any other such relief the Court deems just and proper in the premises.

PLAINTIFF DEMANDS A JURY TRIAL ON ALL COUNTS

Respectfully Submitted,

MONTEE LAW FIRM, P.C.

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